IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	:	Civil Action
Plaintiffs,	:	
v.	:	
BARR LABORATORIES, INC.,	:	
Defendant.	:	No. 06-286-GMS

- - -

Wilmington, Delaware
Thursday, May 22, 2008
9:00 a.m.
Day 4

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
PAUL H. BERGHOFF, ESQ.,
JOSHUA R. RICH, ESQ.,
JEREMY E. NOE, ESQ.,
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ALLISON BALDWIN, ESQ.
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APPEARANCES CONTINUED:

KAREN L. PASCALE, ESQ.
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JAMES HURST, ESQ.,
MAUREEN L. RURKA, ESQ.,
TARAS GRACEY, ESQ.,
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JULIA JOHNSON, ESQ.
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Counsel for Defendant

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THE COURT: Good morning. Please be seated.

(Counsel respond "Good morning.")

THE COURT: Mr. Berghoff.

MR. BERGHOFF: Allison Baldwin will call our second witness on rebuttal.

THE COURT: Good morning, counsel.

MS. BALDWIN: Good morning, Your Honor. Plaintiffs call Brandon Simpson to the stand.

... BRANDON SIMPSON, having been duly sworn as a witness, was examined and testified as follows ...

DIRECT EXAMINATION

BY MS. BALDWIN:

Q. Good morning, Mr. Simpson.

A. Good morning.

MS. BALDWIN: May I approach, Your Honor?

THE COURT: Yes.

BY MS. BALDWIN:

Q. Mr. Simpson, where are you currently employed?

A. My current employer is AstraZeneca Pharmaceuticals.

Q. Before you started work at AstraZeneca Pharmaceuticals, who was your employer?

A. Rhone-Poulenc Rorer.

Q. When did you start at Rhone-Poulenc Rorer?

A. In 1991.

Q. And how long were you there?

A. Approximately eight years. I left, I believe, in 1999.

Q. And for convenience, would you mind if we call it RPR?

A. Please do.

Q. Thank you. During your time at RPR, what position did you hold?

A. While I was there the eight years, I held a number of positions. Initially, I was part of the clinical operations, primarily my function there would be as a CRA or clinical research associate.

Q. And what were your responsibilities as a clinical research associate?

A. The main functions of the CRA were two, actually work in the drug development phase when you were actually carrying out clinical trials. So my functions at that time

be would have been to initiate, monitor clinical trials, all the way through completion, with study reports and ultimately submission to the regulatory authorities.

Q. In your role as a clinical research associate, did you have direct contact with the study sites of a clinical study?

A. Yes, we did.

Q. During your employment at RPR, were you involved with the Nasacort AQ project?

A. Yes.

Q. What was your involvement?

A. It was procedural, as I said, as a CRA. Again I had a number of positions there. But during that time, CRA would be a good description of my activities.

Q. In the binder I have put in front of you, if you could look at PTX-425, I am going to put it up here on the screen, also, to help. Do you recognize that document?

A. Yes, I do.

Q. What is that document?

A. This would be the first page of a protocol for study RD5029Y-305.

Q. Would it be okay if I refer to this as the 305 study?

A. Yes.

Q. On this front page of the study protocol, could you tell me what is in that center paragraph there?

A. **Yes. This was just a standard statement of confidentiality, indicating that this document was confidential and should be held that way, as stated in that language.**

Q. **Did all of the investigators involved in the study receive this document?**

A. **Yes, they did.**

Q. **Did it also contain this confidentiality statement?**

A. **Yes.**

Q. **Could you also look at PTX-192 in your binder. For convenience, I have also put that one up here for you. Can you tell me what this document is?**

A. **Yes. This would be the first page of a comprehensive medical report for the same study 305.**

Q. **Now, were you involved in the clinical trial 305?**

A. **Yes, I was.**

Q. **Were you the CRA for that clinical trial?**

A. **I was one of the CRAs, yes.**

Q. **How long did the 305 trial last?**

A. **For an individual patient study, 305, they were involved for roughly four weeks of actual treatment. The study in toto, as stated on that page, lasted from roughly December of 1992 and completed in March of 1993.**

Q. **So the patients are involved for a much shorter time than what is represented on the front of that actual report**

on the study?
A. That's correct.
Q. Could you look now at PTX-438 for me? I have put that one on the screen for you as well. Could you tell me what this document is?
A. Yes. This would be the first page of the protocol for Protocol No. RD5029Y-309.
Q. And for convenience can we call this one the 309 study?
A. Yes.
Q. And does it contain a confidentiality statement similar to the one we saw previously?
A. That's correct.
Q. And I also noted at the bottom of the page is a little footer. Can you tell me what that says?
A. That is an additional confidential statement that just states, This material is property of Rhone-Poulenc Rorer. Do not disclose or use except as authorized in writing by Rhone-Poulenc Rorer.
This was actually part of our standard stationary that we printed the protocols on.
Q. Now, were you involved in the 309 study?
A. Yes.
Q. And were you the CRA for that study?
A. I was one of the CRAs, yes.

Q. **How long did the 309 study last?**

A. **Participation by the individual patients was roughly three weeks. I would have to look up the exact timing. If you give me a minute, I will.**

The actual timing of the entire study was roughly from August of 1993 through October of 1993.

Q. **Let's talk about the patients in these studies for a moment. What information about the study drug did RPR provide to the patients?**

A. **Basically, the patients received three bits of information. I think we have talked about previously they received the informed consent. They also received the patient diaries, where they were allowed to record their symptoms. And then the last piece was actually a label that is actually affixed to the study medication that they received.**

Q. **Let's talk about these different pieces of information. Let's first talk about, you mentioned the informed consent form?**

A. **Yes.**

Q. **Could you look at PTX-192 at Page 34252?**

A. **Yes.**

Q. **Here it is for us. Is this an example of a patient information and consent form?**

A. **Yes. This would represent the first page of several.**

Q. **And which study is this one for?**
A. **This is for Study 305. This particular version was for Dr. Koepka.**
Q. **In the title it mentions RG5029Y. What does that designate?**
A. **That was the internal designation for the TAA aqueous product.**
Q. **So this was the internal designation for the product that became Nasacort AQ?**
A. **That's correct.**
Q. **Okay. Now, what is the purpose of this information consent form?**
A. **The patient informed consent is intended to provide information to the patient about the benefit risk. It should also include the information that they need to understand about their participation in the study so it outlines be exactly what they will be asked to do. It also has contact information in the event they should need to contact the study center at any time during participation in the study.**
Q. **Now, do all patients have to sign this consent form?**
A. **Yes, that is a requirement.**
Q. **What information does the informed consent form give the patient about the study drug itself?**
A. **It's very limited. As you can see here actually in**

the title, it does list the active component of the study component. Other than that, it does explain that they could be receiving active but they could also be receiving placebo so they wouldn't know actually which one they would be receiving.

Q. So some of the patients don't have -- although they're in the study for TAA, they don't even have TAA in the drug that they receive. Is that correct?

A. That's correct. The study in the title doesn't explain it but within the protocol, it does explain that this is a double blind placebo controlled study.

Q. What information do the patients receive about the formulation itself of the study drug?

A. Other than it was a water based product, I don't believe there was additional information.

Q. Now, does this patient information consent form control the patient's use of the drug?

A. They are instructed how and when to take.

THE COURT: Wait. Wait. Counsel, could you be more specific?

MS. BALDWIN: I was just trying not to lead.

THE COURT: You don't have to lead to ask a question.

MS. BALDWIN: Okay.

BY MS. BALDWIN:

Q. **Does this patient information consent form control who can take the study drug? And I'll refer you to, if you look the PTX-192, Page 34256. It might help you.**

A. **Yes. In an individual study, it would, as part of the description, indicate that the patient should only, the study drug should only be taken by the patient to who it was assigned. And this was an informed consent that would be signed by an individual patient. Therefore, as it says here, the study medication must be only taken by that person for whom it has been prescribed.**

Q. **So the patients know the study drug is only for them?**

A. **That's correct.**

Q. **Let's also talk about a second piece of information you mentioned was the patient diary form. And I think an example of that in that same exhibit, here at NIQ 34245. Is this one of the diary forms?**

A. **This is an example of a diary, yes.**

Q. **What information does this diary form give the patient about the drug that they are taking?**

A. **I think you can see just under the month statement up there, it actually tells them to, on a daily basis, record the total numbers of study, number of medications of spray they took on each individual day. It's set up as a calendar so they can actually just note that on each individual day.**

Q. **So patients actually have to monitor the amount of**

drug they used each day?
A. In numbers of sprays, yes.
Q. Is there any other information on -- I'm sorry. Yes. Is there any other information on this form that tells them anything about the formulation of the study drug?
A. No.
Q. And I think its third piece of information you mentioned was the product label itself?
A. Yes.
Q. That's the label that is actually on the bottle they receive?
A. That's correct.
Q. Okay. Do you recall what is on that label?
A. I don't remember the specific components. I know that is regulated by federal guidance. I don't remember the number but there is basic information that is required to be on there: numbers of sprays, storage conditions. I'm blanking on the other parts right now but there is a guidance that does allow us to -- that has the core basic information that must be there.
Q. Now, earlier you mentioned that some of the patients will actually be receiving placebo and some will be receiving the study drug. Are the labels different for the placebo vs. the study drug?
A. No. That is the whole intent of doing a blinded

study. The bottles themselves are as identical as possible so that there is no distinction between the two products.

Q. Is there anything on the label that lets the patient know that this is an investigational drug?

A. Again, I don't recall the exact verbiage. There may be statement to that effect but I don't recall exactly what the verbiage is.

Q. So is there any other information the patients are given?

A. Those would be -- those three documents we just described would be the information that the patient received.

Q. Now, can a principal investigator give the study drug to one of his patients who is not a part of the actual study?

A. Absolutely not.

Q. So they can only give a drug to someone who has signed one of these patient information consent forms?

A. That's correct.

Q. Let's talk a little bit about your role in this study. What steps does RPR take to control the clinical studies as they are ongoing?

A. Well, once the studies are approved, there are a number of steps of control. Probably the first one would actually be a joint meeting, investigators meeting where we

bring all centers together and actually go through the steps as we would expect then to carry out so it's very clear what our expectations as a company would be and how we expect them to conduct business.

As the study progresses, there are multiple monitoring visits where, as I said earlier, the CRAs would actually go to the centers, review the documents to make sure that the appropriate information was being correctly collected. There was some transcription between patient information into what is called a case report form which is actually the document the company retrieves for building the database of the actual information.

Along with that is drug accountability. There are certain guidelines that go along with that as well. That was one of the functions of the monitor was to make sure that the drug was being appropriately monitored both when it was dispensed, to whom it was dispensed, how many bottles were dispensed, the date and also when those bottles were returned. That that was also logged into that. And that was part of the standard process.

Q. You talk about drug accountability in that long list of things that you would do. Did you have to account for every single bottle of study drug that was used in the clinical trial?

A. Yes.

Q. **Do you actually have to account for the amount of study drug that is in the bottle as well?**

A. **The actual amount used was taken from the patient diary. So as we asked the patients to record the number of sprays each day, that was an attempt to somewhat understand the compliance issue. There was a limited amount of numbers of sprays within the bottle itself so it wasn't as if it was a year supply or something like that.**

Q. **Now, how did you do this monitoring that you mentioned? Did you actually visit the study sites to do that?**

A. **That's correct.**

Q. **And if you look at PTX-194 in that binder of yours.**

A. **(Witness complies.)**

MS. BALDWIN: If you could pull it up for me, Eric.

BY MS. BALDWIN:

Q. **What is this document, Mr. Simpson?**

A. **Yes. This is an internal Rhone-Poulenc Rorer document that was at each individual investigative site. This one, as you can see in the header area there, was at one of the sites for Protocol Study 305. As a monitor, we were required to sign this document each time we visited the investigator for a monitoring visit. And this was kept with the documents for that particular study. So each time I**

visited, as you can see a number of times, I was required to sign this document.

Q. That's actually your signature there then?

A. That's correct.

Q. And when you actually went to the study site and reviewed this, did you fill out -- I think you mentioned you filled out a report at the site.

A. Yes. This was kind of a sign-in log. We would actually do our activities at the site. But then once we would return, we were required to complete a monitoring visit report. Again, it was an internal document that we required for each visit.

Q. If you look at 195 in that binder in front of you. Is that an example of one of the reports?

A. Yes, that would be Page 1.

Q. Now, Mr. Simpson, the one other group I would like to talk about are the investigators themselves. Now, were the investigators under any sort of confidentiality agreement with RPR?

A. Yes, they were.

Q. And if you will look at PTX-191. What is this document?

A. This would be the first page of a confidential disclosure agreement between one of the investigators and Rhone-Poulenc Rorer.

Q. **Did every principal investigator have to sign one of these documents?**

A. **Yes. Our standard operating procedure at that time would be that this would actually be the first document that would be reviewed and agreed upon with the investigator before we would actually allow them to review any of the other information about the compound or the study.**

Q. **So this was always step one before anything was sent to the investigator?**

A. **That was our operating process, absolutely.**

Q. **Is this disclosure agreement limited to the study itself?**

A. **No. These agreements were typically put in place for a compound. It just expedited things, so if an investigator did a number of studies with the same compound they would be covered under the same disclosure.**

Q. **Were these disclosure agreements only with the investigator?**

A. **Yes. My understanding is it was between the investigator and Rhone-Poulenc Rorer.**

Q. **Were the people working under him bound by this agreement?**

A. **The people reporting to the investigators understood that he is accountable for their actions. So certainly during the course of the study he has to share information**

with his staff to carry out the study. But it is understood that he is responsible for their actions.

Q. One last document I would like for you to look at, PTX-196. Do you recognize this document, Mr. Simpson?

A. Yes. This was a declaration that I signed.

Q. Does this declaration discuss the information you have just provided to the Court regarding clinical studies 305 and 309?

A. Yes.

Q. Did you sign this declaration?

A. Yes, I did.

Q. Did you confirm that everything in this declaration was accurate before you signed it?

A. Yes, I did.

Q. Is there anything in this declaration that is inconsistent with the information you have provided to the Court today?

A. No, there is not.

MS. BALDWIN: I have no further questions.

THE COURT: Ms. Rurka, you may cross-examine.

CROSS-EXAMINATION

BY MS. RURKA:

Q. Good morning, Mr. Simpson.

A. Good morning.

Q. Could you please pull up DX-2, which I think is the

declaration we were just looking at. Does this declaration tell the Patent Office that the Nasacort AQ had been reduced to practice as of May 1, 1992?

A. I would have to read through it. I don't know the exact answer, without having reread it.

MS. BALDWIN: Objection. Calls for a legal conclusion about reduction to practice.

MS. RURKA: It calls for a conclusion about what the declaration tells --

THE COURT: Hold on a second, counsel. She is objecting. I can't rule.

I am going to overrule the objection. I think actually Ms. Rurka is correct. I am going to overrule the objection.

THE WITNESS: Can I read through?

BY MS. RURKA:

Q. Feel free to look.

A. Can you restate the question?

Q. The declaration does not tell the Patent Office that Nasacort AQ had been reduced to practice or the claimed invention had been reduced to practice as of May 1st, 1992, did it?

A. Can you explain reduced to practice?

THE COURT: She is just asking you, sir, what the declaration says. You really don't need to know what

reduced to practice means to answer this question. Just read the declaration, see what you see.

If at the end of the day you can't answer it, just say, I am unable to answer it, that's fine.

(Pause.)

THE WITNESS: Okay. State one more time and I will do the best I can.

BY MS. RURKA:

Q. **Of course. The declaration does not tell the Patent Office that the subject of the patent application, the claimed invention, was reduced to practice as of May 1st, 1992, does it?**

A. **I don't understand that now.**

THE COURT: That's fine.

BY MS. RURKA:

Q. **You testified that you oversaw the 305 and 309 studies?**

A. **That's correct.**

Q. **They tested the safety and efficacy of Nasacort AQ?**

A. **That was one of the objectives of the study, yes.**

Q. **The results of those clinical trials were submitted to FDA to support approval of Nasacort AQ?**

A. **Yes.**

Q. **I think you testified that the 305 clinical trials, the 305 studies were performed from December '92 through**

March 1993. Is that right?

A. **Let me verify.**

Q. **Please do.**

A. **Study 305?**

Q. **305.**

A. **Yes, I have the study start date of December of 1992 through March of 1993.**

Q. **And that study involved the administration of Nasacort AQ to 178 volunteers. Is that correct?**

A. **There were 178 total patients but they received two treatments.**

Q. **Okay. Thank you. And the 305 study that was performed from August through October of 1993 -- I think you testified?**

A. **I think that's correct.**

Q. **If you need to verify that...**

A. **Let me verify and look.**

Q. **Absolutely.**

A. **Yes. For Study 309 the start would have been August of 1993. Completion was October of 1993.**

Q. **And that involved administration of Nasacort AQ to I think 429 volunteers. Is that right?**

A. **Yes. Again, under the same study design, it was split between active and placebo, yes.**

Q. **Would you please pull up Demonstrative 49. And here**

is the dates I think you just testified to. December 1992 through May 1993, that was the 305 study, 178 patients were studied there. And then August of '93 to October of '93, there were 429 patients. Does that look right?

A. **That looks correct.**

Q. **And the patients were allowed to leave the facility with the drug product they were given. Correct?**

A. **Yes.**

Q. **And they were self-administering the product. Is that right?**

A. **Yes.**

Q. **There were no restrictions on where they could use the product. Right?**

A. **Not that I am aware of, no.**

Q. **And they were told that they were taking TAA. Correct?**

A. **No.**

Q. **They weren't?**

A. **They were told that was a possibility. But again, it was a blinded trial, so they knew the two options but they did not know what they were actually taking.**

Q. **But they did know they could be taking TAA?**

A. **Yes.**

Q. **And they knew it could be a TAA aqueous formulation. Right?**

A. **Their informed consent, I believe, referred to it as a water substance or something. I don't remember the exact language.**

Q. **They were told that it was an aqueous or water-based formulation. Right?**

A. **That was part of the informed consent, yes.**

Q. **None of the patients signed confidentiality obligations, did they?**

A. **Not to my knowledge.**

Q. **There were no implied confidentiality obligations on the part of the patients?**

A. **Other than what we showed earlier, they were instructed to not share the medication with another patient or family member or something like that. But that would pretty much be the extent of it.**

Q. **But they could tell somebody they were taking an aqueous TAA?**

A. **We asked them not to. But, I mean, we didn't follow them around.**

Q. **They were not legally obligated to say nothing about what they were taking?**

A. **That's correct.**

Q. **The two studies, the 305 and 309 studies were published* in papers before July of 1995. Correct?**

A. **I believe that's correct. I don't know that I have**

the exact dates in here. I would have to look at the actual publication to be able to give you that exact information.

Q. Could we pull up DX-10 and 11 together.

So on the left here, we have DX-10. That is the 309 study. Correct?

A. Yes, it is.

Q. And on the right is DX-11. That is the 305 study?

A. That's right.

Q. Could you turn to the last page. So that shows that the Kobayashi paper is May to June of 1995. Right?

A. That's correct.

Q. And the second-to-last page.

MS. RURKA: Could you blow up the top right? It's a little hard to read.

BY MS. RURKA:

Q. Does that look like March through April of 1995?

A. My goodness. Look at that.

Q. It was published in 1995. Right?

A. I believe that is correct.

MS. RURKA: All right. Why don't we pull the time line back up. Could you put the papers on there?

BY MS. RURKA:

Q. So some time in 1995, these papers are published. Correct?

A. Yes.

Q. **And you published these, RPR published papers with the intention of using them for marketing. Correct?**

A. **The intent, as I recall it, was for more of a scientific point of view to actually have that new information in the public domain. These articles sometimes are used for marketing purposes, of course.**

Q. **Okay. Did RPR want to make the public aware of a new product that was coming out on to the market?**

A. **I'm not aware that that was the purpose of these publications.**

MS. RURKA: Can we pull up the Simpson deposition.

BY MS. RURKA:

Q. **You were deposed in this case?**

A. **That's correct.**

MS. RURKA: Can you pull up the transcript at Page 139?

BY MS. RURKA:

Q. **It says here:**

"Question: Do you have an understanding as to why you were publishing the results of clinical study 309?

"Answer: Yes.

"Question: And what was that understanding?

"Answer: In general, to get the information out there. It's obviously of some scientific value as well as

so that the more general public would be -- begin to be aware of a possible new product that would be coming on to the market.

"Question: And why -- why was that important?

"Answer: Um, my personal feeling about that would be, as any new product would come on the market, the more widely known or understood it is, then the more likely its acceptance would be."

Did you answer the questions that way at your deposition?

A. Yes, I did.

MS. RURKA: Can we put up PTX-1, please?

BY MS. RURKA:

Q. Do you recognize this document?

A. I see it. But it doesn't completely ring a bell, no.

MS. RURKA: Actually, why don't you pull up the filed date there on the left-hand side.

BY MS. RURKA:

Q. And this patent was filed on July 3rd, 1996. Right? Is that what it says?

A. According to that, yes.

MS. RURKA: Why don't we pull back up Demonstrative 49.

And can we put that date on there?

BY MS. RURKA:

Q. **So July 3rd, 1996 is the date that was on the front of that patent. Correct?**

A. **Yes.**

Q. **And you submitted the declaration to the Patent Office. I think we talked about that earlier. Right?**

A. **Are you asking for a date or just a yes/no?**

Q. **Just yes/no.**

A. **Yes.**

Q. **In that declaration, you told the Patent Office that the Settipane and Kobayashi clinical trials were performed on the claimed invention. Right?**

A. **Yes.**

MS. RURKA: Nothing further. Thank you.

THE COURT: Redirect.

MS. BALDWIN: Just a couple of questions, Mr. Simpson.

REDIRECT EXAMINATION

BY MS. BALDWIN:

Q. **For the 305 Study, how long did the patient actually have the study drug in their possession?**

A. **For Study 305, that was a four-week treatment. So the patient would have the study medication for a total of four weeks.**

Q. **And how much medication do they have during that four weeks?**

A. **They would have had I believe a single bottle. I don't recall the actual volume. It had to have at least 120 sprays in, and that works out to I think a very small amount, maybe one milliliter or something like that.**

Q. **Is it the same size as the commercial Nasacort AQ bottle?**

A. **I can't answer it. I don't know exactly the comparisons between the two. It would be certainly generally very much like that, yes.**

Q. **And for the 309 Study, how long did the patient actually have the study drug in their possession?**

A. **That would have been no more than three weeks.**

Q. **And for the bottles of the study drug in the same tine of containers that they were in the 305 Study?**

A. **That's my recollection, yes.**

MS. BALDWIN: Thank you. No further questions.

THE COURT: All right. Thank you, sir.

MR. NOE: Good morning, Your Honor. Plaintiffs next call Dr. Bell.

THE COURT: Good morning.

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PLAINTIFF'S TESTIMONY

... DR. GREGORY KNOX BELL, having been placed under oath at 9:45 a.m. as a witness, was examined and testified as follows ....

- - -

MR. NOE: May I approach, Your Honor?

THE COURT: You may.

(Binders passed forward.)

DIRECT EXAMINATION

BY MR. NOE:

Q. **Good morning, Dr. Bell. Could you please state your full name for the record?**

A. **Gregory Knox, K-N-O-X, Bell.**

Q. **Dr. Bell, please briefly describe your educational background?**

A. **I have a Bachelor's of Arts, major in Economics, minor in Business, First Class Honors from Simon Fraser University in Canada. Master's in Business Administration with highest distinctions from Harvard and Ph.D. in Business Economics from Harvard University.**

Q. **Do you have any other professional degrees?**

A. **I'm also a Chartered Accountant in Canada. That's the same things as a CPA, Certified Public Accountant here in the U.S.**

Q. **How are you currently employed?**

A. **I'm the Executive Vice President in charge of Strategy and Business Consulting at CRA International. CRA International is a global economics and management consulting firm.**

Q. **Have you held any other positions at CRA?**

A. **I'm also the Practice Leader for the Global Life Sciences practice. That position I've had for about the past 15 years.**

Q. **Within the Global Life Sciences practice, what are your responsibilities at CRA?**

A. **Well, they're principally two different types of responsibilities. The first is, one is doing this kind of work as an expert witness in proceedings dealing with the economics of the Life Sciences industry: patent cases, antitrust issues, other commercial disputes.**

But the majority of my work is in business strategy consulting. I would be hired by major life sciences firms and global multinational pharmaceutical companies to help them assess, for instance, the opportunity for a new drug, a new indication, a new therapy, help bring that therapy to market, issues around launch strategy, how to price the product, how to market it, how to position it for physicians, position it for patients, what attributes are likely to drive physician prescribing behavior for that product, patient use behavior, how competitors would be expected to respond in the marketplace to their launch of this product. And then following the product through the life cycle: when somebody else is entering a new product or when the product in a category goes generic or potentially

over-the-counter therapy comes up.
Q. Can you provide examples of some of the pharmaceutical companies you have worked with in the past?
A. Sure. It's the standard list of all the major ones: Bristol Myers Squibb, Johnson & Johnson, Eli Lilly, Sanofi-Aventis, Genzyme, Genentech. Pretty standard list.
Q. Have you held any academic positions?
A. Yes. I've lectured at Harvard University where I developed a course on the economics of business strategy. And then also as a Visiting Assisting Professor at Northeastern University in the Economics faculty prior to joining CRA.
Q. Do you have any publications?
A. Sure. They would be publications dealing with my academic research, issues around how companies make investment decisions, real options, that sort of thing. And then obviously with respect to the pharmaceutical industry, issues around pricing, cost effectiveness of drugs, that sort of thing.
Q. Have you been retained before in patent litigation where you were asked to offer an opinion on commercial success?
A. Yes, I have.
MR. NOE: Your Honor, at this time, plaintiffs offer Dr. Greg Bell as an expert in the economics and

commercial strategies of the pharmaceutical industry.

THE COURT: Any objection?

MS. JOHNSON: No objection.

THE COURT: The doctor is accepted as an expert in these fields.

BY MR. NOE:

Q. Dr. Bell, what you were asked to do in this litigation?

A. I was asked to address two issues: First of all, whether or not Nasacort AQ was a commercial success from the perspective of nonobviousness as a secondary indicator. And then, secondly, whether or not that commercial success system from a nexus with respect to the patented attributes of the product.

Q. In your opinion, what are the issues related to evaluating commercial success as a secondary consideration of non-obviousness?

A. Well, first of all, it should be the case that we are talking about the product that is embodying the innovation at issue or potentially the product is the innovation at issue.

It should be the case that it is able to secure demand in the marketplace that is sufficient to support a price in the marketplace that is more than adequate to compensate for the ongoing costs of manufacturing the

product and marketing the product.

And then secondarily, the second issue is, given that commercial success, the question is, has that commercial success been due to patented attributes or potentially due to other actions on behalf of the company that's commercializing the product.

So, for instance, it might be the case that the product had an inordinately low price in comparison to the competition. And that might be what is driving a lot of the demand. Or it could be that the product has been advertised, promoted, inordinately heavily, again, as compared to the competition. And that might be what's driving the success.

Q. **What did you rely upon in forming your opinions in this case?**

A. **Well, certainly, there is my experience in the industry, 15 years leading the global practice at Searle, my expertise, in terms of the economics of business strategy. And then specifically, obviously, in this case, I reviewed the patents, reviewed a lot of documentation that has been produced by Sanofi-Aventis around the marketing strategy for this product, how it's being positioned for physicians and patients and payors, financial information on the product and summaries of how the product has performed.**

And then IMS and Verispan data. These are two

companies that provide data to the pharmaceutical industry around sales and marketing expenditures and the like.

Q. Dr. Bell, in your opinion, has Nasacort been a commercial success in the context of non-obviousness?

A. Yes, Nasacort AQ has been a commercial success in the context of non-obviousness, from my perspective.

Q. What is the basis for that opinion?

A. Well, there is really probably four of them. First, the product has engendered significant and substantial demand in the marketplace. Aventis has realized revenue in excess of one and a half billion dollars for this product since its launch.

Secondly, it's a product that's earned a growing share of prescriptions in the intranasal corticosteroid category, even at a time when that category has been growing.

Thirdly, it's been a product that's actually had to confront some obstacles. In principle, there were two significant supply disruptions that affected, obviously, the supply of the Nasacort AQ at the pharmacy. And yet demand for the product was sufficiently persistent that sales built back up after those supply disruptions were addressed, physicians continuing to demand to prescribe this product and patients continuing to use it.

Fourthly is, of course, the profitability. This

is a product that has significantly performed, from the perspective of compensating or paying for all the costs of, ongoing costs of manufacturing and marketing the product and is contributing to the profits of Sanofi-Aventis, one of world's largest pharmaceutical companies.

Q. Let's take each of those one at a time. First, how did you learn that there have been substantial sales of Nasacort AQ?

A. Well, here, I looked at the IMS data, which again is this company that provides the information on the pharmaceutical industry, and simply plotted the sales, as recorded by IMS of Nasacort AQ.

Q. Can we pull up Nasacort AQ.

Dr. Bell, is this an exhibit you prepared?

A. Yes, it is. And again, you can see on the left-hand axis, that is the sales dollars as recorded by IMS by year since the launch in 1996. And as you can see, according to IMS, Nasacort AQ has generated over 2.3 billion dollars in sales.

That is 38 million prescriptions that have been written for this drug, that physicians have written and that patients have filled since it was launched in 1996.

Q. And, Dr. Bell, is this an exhibit that you prepared based on information that's contained in your expert report?

A. Yes. As you can see at the bottom, this is

information that's taken directly from Schedule 3.1 in my expert report, which is the IMS sales data for the products in the intranasal corticosteroid category.

Q. Turning to the second basis of your opinion that Nasacort AQ was commercially successful, how did you determine that Nasacort AQ share increased over time in a growing market?

A. Well, again, I used the IMS data, which is tracking the sales of all the products in the category, and here looked at Nasacort AQ's share of prescriptions as a percentage of all prescriptions that were issued in -- or fulfilled, rather, in the intranasal corticosteroid category.

Q. Can we call up Plaintiffs' Demonstrative 29, please.

Dr. Bell, is this another exhibit that you prepared?

A. Yes. As you can see, this one is taken from Schedules 1.1 and 1.2 of my expert report. Again, on the y axis, or the vertical axis, we have got the share of prescriptions. And you can see that year on year, it generally has increased for Nasacort AQ, reaching a peak of 14.4 percent of all prescriptions in the intranasal corticosteroid category in 2004.

So given this increase in prescriptions over time, I looked at the growth rates, to see how fast, for

instance, the Nasacort AQ prescriptions were growing and how fast the prescriptions for the category as a whole were growing.

What I find is from 1997, the year after launch, through to 2006, prescriptions for Nasacort AQ are growing at 11.4 percent, more than twice as fast as prescriptions are growing for the category as a whole.

Now, to me that obviously indicates that this is a product that the growth and demand of this specific product is significantly higher than the growth and demand for the category as a whole, clearly indicated a differentiated product in the marketplace that physicians are prescribing for and that patients are using.

Q. Dr. Bell, for the third basis of your opinion on commercial success, how did you conclude that there has been a sustained and growing demand for Nasacort AQ despite obstacles?

A. Well, again, I have looked at the IMS data, and in particular focused around two periods where there were supply chain interruptions that had been reported in the documentation from Sanofi-Aventis. These were disruptions in the supply chains such that the expected amounts of Nasacort AQ weren't moving through the pipeline, going from the manufacturer to the wholesaler to the retailer and able to be dispensed to the consumer.

Q. **Can you call up Plaintiffs' Demonstrative 30, please.**

Dr. Bell, is this another exhibit you prepared?

A. **Yes, it is. And as you can see, this is taken from Schedule 5.2 of my expert report. Again, on the vertical axis, that's the share of prescriptions. And this is data that is actually done at the monthly level. So I looked at the monthly prescriptions for Nasacort AQ as compared to the monthly prescriptions for all intranasal corticosteroids. And you can really see here where those two green arrows are the impact of the supply chain interruptions.**

Obviously, if product isn't getting to the retailer, it can't be dispensed to patients. So you see at the start of 1998 and again at the start of the 2000 a significant drop in the share of all prescriptions that were Nasacort AQ prescriptions.

What I think is significant about this is that the demand for this product has obviously persisted. After those supply chain interruptions have been corrected, you can see that the share of prescriptions climbs back up again and, in fact, surpasses the previous level.

That is indicating to me, again, demand for this product, this product in the category, by the physicians who are prescribing it and patients who are using it.

Q. **For the fourth basis for your opinion on commercial success, how did you determine that Nasacort AQ sales have**

helped generate profits for Aventis?

A. Well, here I looked at the financial information that had been prepared in the regular course of business by Aventis with respect to the product contribution or the contribution to profits for the Nasacort AQ product.

Q. Can we have plaintiff Plaintiffs' Demonstrative 31, please.

Dr. Bell, is this another exhibit that you prepared?

A. Yes, it is. Again, this is from my expert report. This one is Schedule 4.1 of my expert report. It is a fairly standard presentation of financial results. You can see, we start with sales at the top line, and then we have got a margin, which is the result of deducting costs of sales.

Then there is the marketing, direct marketing expenses for the product, and direct ongoing research expenses for the product. And then we have got the consequent product contribution, which is the margin less those direct expenses. Then that product contribution percent is simply what's the return on the net sales that the product is realizing to the profits of Sanofi-Aventis.

What is important and what we have obviously called up here on the demonstrative is, for instance, that the last three years, which are the three years that I have

data that is specific to Nasacort AQ, you can see that the sales of this product are dropping to the bottom line of Aventis or contributing to the bottom line of Aventis more than 50 percent of those sales values.

So, clearly, again, here is sales of product able to command a price in the marketplace, able to generate unit sales that more than cover, obviously, what it costs to manufacture and on an ongoing basis market the product.

Q. You can take this down.

Dr. Bell, turning to the issue of nexus. In your opinion, is the commercial success of Nasacort AQ linked to the patented features of that product?

A. Yes, it is.

Q. What is the basis for that opinion?

A. Well, fundamentally, it's got to do with how Sanofi-Aventis has marketed and positioned and messaged, if you will, the product in the marketplace, how it is talked about, the attributes of this product, to physicians and to patients. That message go has been tied back to the attributes of the products.

Then I go further and look at, okay, but is it the case that the product, Nasacort AQ, has benefited inordinately because of extraordinary expenditures by Sanofi-Aventis on marketing this product, in comparison to the competitors in the intranasal corticosteroid category,

or has it been the case that Sanofi-Aventis has been able to benefit this product by having a significantly lower price and as a result generating lots of unit sales in comparison to the competitors.

That is the information that I use in reaching my conclusions.

Q. What is your understanding of the patented features of the product?

A. Well, first and foremost, it's my understanding that the product itself is the embodiment of the patented features. It is TAA, the active ingredient in aqueous. It is such that it's providing that the once-a-day efficacy and relief from symptoms.

The thixotropic property, which, as I understand it, enables this product to be sprayed and then to stay where it's sprayed, as one of the tag lines read. And as a result, giving the active ingredient the time to penetrate the mucosal membrane and work.

It's odorless. And that's stemming from the fact of it being alcohol free, that phenylethyl alcohol that gave the sort of rose scent. Tasteless.

And those attributes are contributing to patient comfort.

And the fact that it's not delivered with an aerosol blast but this soft poof.

So these issues of the once-a-day efficacy, the nature of it, the odorlessness, patient comfort. Those are all elements of that patented claims.

Q. Dr. Bell, how did you conclude that the market messaging for Nasacort AQ is linked to the patented features of that product?

A. Well, there is a fair amount of information in the production about exactly how Sanofi-Aventis was positioning the product in the marketplace and what the core messages were that they were planning to have transmitted to the physicians and to the patients and were the basis, for instance, for advertising campaigns and the messaging that the sales representatives would have at the top of their mind when they go and visit the physicians.

MR. NOE: Could we call up Plaintiffs' Trial Exhibit 608, please?

BY MR. NOE:

Q. Dr. Bell, is this one of the documents you just referred to?

A. Yes, it is. This is certainly one of the documents from the production that I relied upon. And you can see, for instance, in the top left there, it talks about the positioning. And so this is the idea about how is it that as a brand, we're going to position ourselves in the marketplace in order to differentiate ourselves in the

marketplace, provide something for the physicians to remember when they're looking to prescribe this product.

And so we've got this point here: stays where it's sprayed, relating to the thixotropic formulation.

The QD or once-daily dosing is obviously important from a patient's convenience perspective, and enabled by the fact that this is TAA in aqueous.

The odorlessness that comes from the lack of phenylethyl alcohol.

So that's how the brand and the brand managers and Sanofi-Aventis are looking to position the product in the marketplace.

And then if you look over at the middle of the second page, you see the core messages that they were looking to convey that positioning statement. So the core messages were: Stays where it's sprayed. The thixotropic nature. As a result, minimal drift at the back of the throat or runoff. The odorlessness of the formulation. The once daily dosage providing relief coming from the TAA that is being administered.

Q. Dr. Bell, in your opinion, did Aventis spend disproportionally to market these attributes?

A. No, it did not. And that is something I looked at.

MR. NOE: Can we call up Plaintiffs' Demonstrative 35, please?

BY MR. NOE:

Q. **Dr. Bell, is this an exhibit that you prepared?**

A. **It is. You can see again this is taken from my expert report. This is Schedule 3.6. And what this is doing is or what is on the Schedule 3.6 for that matter is the total of promotional expenditures as tracked by a company called Verispan.**

And these are promotional expenditures for the detail representatives. Those are the sales representatives that go out and visit the physician's office. The ongoing medical education that the company would support. Physician conferences. Advertising in medical journals. Direct-to-consumer advertising that you might see on the television or in a consumer magazine.

And what I have looked at is say, okay, for the first nine years on the market, obviously, for Nasacort AQ and the three principal competitors for which I have the data on the first nine years on the market. What you see is according to Verispan, Nasacort AQ has actually spent less than its principal competitors. So clearly, it's not the case that Nasacort AQ or Sanofi-Aventis on behalf of Nasacort AQ has outspent the competition to try and drive sales for the product.

Q. **Is this exhibit based on actual financial data from Aventis?**

A. **Well, no, it isn't. And the reason, of course, is because we don't have the actual financial information for the competing products. And this is the standard issue in the pharmaceutical industry. And so everybody uses Verispan, IMS data on how the competitors are spending.**

The issue isn't so much the absolute levels. The question is, you know, according to Verispan, am I spending as much as my competitor? Am I spending 20 percent more? Am I spending 20 percent less? And that information is what the brand manager uses to adjust the marketing program as they go forward.

Maybe we need to be making more calls with physicians, because the competitors are in the offices much more often than we are, or they're spending a lot more on journal advertising so that the product is getting in front of physicians more often. So everybody uses these measures.

And maybe it would help to just explain a little bit. The way they do this is a little bit like the way Neilsen does TV ratings. They've got a panel of physicians. And this is a panel that obviously rotates. And the physicians, for instance, record every time a rep, a sales representative comes into the office and what product they talk about and what order they talk about them in. And then Verispan takes all that information, grosses it up to the size of the market, multiplies by a standard cost for a rep

and that is sort of the detail expenditures part of this measure.

So is it exactly correct? Of course not. But to the extent there is errors, the errors are the same for every competitor and so that is why we use this information when we're looking at how are we comparing against the competition with respect to promotional expenditures, for instance.

Q. Dr. Bell, in forming your opinions that Aventis did not spend disproportionately to support sales of Nasacort AQ, did you analyze marketing and promotion data in any other ways?

A. Sure. The other principal metric is to look at what are the sales dollars as measured by IMS that are generated from those promotional expenditures as measured by Verispan.

MR. NOE: If we can call up -- I'm sorry. I didn't mean --

A. (Continuing): So that's something that I reviewed and have prepared a demonstrative on.

MR. NOE: If we could call up Plaintiffs' Demonstrative 32, please.

BY MR. NOE:

Q. Dr. Bell, is this the exhibit that you just referred to?

A. Yes, it is. Again, you can see this is taken from my

expert report. This is the information from Schedule 2.1. And what is important here is the point that Nasacort AQ, in comparison to Nasonex, Flonase, Rhinocort Aqua, has sales per dollar spent on promotions that's right in line with the competition. It's actually doing a little bit better than Nasonex and Flonase.

And again, these are the sales data for IMS and promotional dollars per Verispan. It's not going to relate directly to information in Aventis financial statements. No one would expect that it would. But what is important is again how does it compare to the competition. Because they're all being measured the same way. And one of the takeaways you would have with something like this is if one of these bars were very low, then you would be saying, aha, that is a situation where the company is putting a lot more in marketing and in advertising to get a dollar of sales than the competition. Perhaps that indicates that marketing and advertising expenditures are a lot more important to the commercial success of this product than the patented features.

Obviously, not the case here.

Q. **What, if anything, did you conclude from your analysis of marketing and promotional expenditures on behalf of Nasacort AQ?**

A. **Well, with respect to Nasacort AQ, commercial success**

has not been unduly influenced by marketing and promotion high school expenditures. Those expenditures have been in line with the competition. And as a result, the success that Nasacort AQ has realized, the demand for this product in my opinion has been coming from the patented features.

Q. In your opinion, did Aventis price Nasacort AQ more aggressively than the competition?

A. No, I don't believe it did. And we flashed up here on the screen another demonstrative. This is one I prepared from Schedule 4.3 of my expert report. And what I'm looking at here is the list price per day of therapy. You know, there could be different dosing for each product. Look at a day of therapy. And it's looking at Nasacort AQ; the principal competitors, Flonase, Nasonex, Rhinocort Aqua and also Beconase and Vancenase because at the time of the launch of Nasacort AQ, they were the lead products in the category.

And what you see here obviously is that Nasacort AQ has not been priced lower than the competition. It's right in the range of the competition. And as a result, from that I conclude that it's not the case that commercial success of Nasacort AQ has been unduly influenced by a particularly low price in comparison to the competition. In fact, the demand for this product is demand for those attributes that it brings to the marketplace. And the

demand that physicians are looking for, the attributes that physicians ar looking for when they're prescribing the product and when patients are using it.

MR. NOE: No further questions at this time, Your Honor.

THE COURT: Counsel.

MR. HURST: Your Honor, Julia Johnson from our office is going to conduct the cross-examination.

THE COURT: Counsel.

CROSS-EXAMINATION

BY MS. JOHNSON:

Q. Good morning, Dr. Bell.

A. Good morning.

Q. My name is Julia Johnson. I represent Barr Labs. This is our first time meeting, isn't it?

A. It is, yes.

Q. Dr. Bell, you testified you reviewed a lot of documents from Aventis regarding their marketing strategy. Correct?

A. Yes.

Q. And in all of those Aventis documents that you reviewed, you didn't see any evidence that Aventis marketed Nasacort AQ on the basis that it deposits in the frontal sinus, did you?

A. Not that I recall.

Q. **So, just, for example, you don't recall seeing any sales training manuals discussing how to market Nasacort AQ on the basis that it deposits in the frontal sinus, do you?**
A. **I don't recall seeing anything specific about that in a sales training manual.**
Q. **You don't recall seeing any marketing materials directed to doctors discussing Nasacort AQ depositing in the frontal sinus, do you?**
A. **Not that I recall, no.**
Q. **And similarly, you don't recall seeing any marketing materials directed to consumers discussing Nasacort AQ depositing in the frontal sinus, do you?**
A. **Not that I recall, no.**
Q. **Okay. Dr. Bell, we heard you testify that you are an economist. Correct?**
A. **Yes.**
Q. **You testify quite a bit about your consulting work that you do. Isn't that right?**
A. **I certainly testify that I do consulting work, yes.**
Q. **But you have never held a position in marketing in a pharmaceutical company as an employee of that company, have you?**
A. **No. I am hired by them to assist on those issues.**
Q. **But you are not an employee of a pharmaceutical company in their marketing department. Right?**

A. **No, I am not.**
Q. **And you have never held the position in sales in a pharmaceutical company as an employee of that company?**
A. **No.**
Q. **And you have never actually held any position in a pharmaceutical company as an employee of that company. Right?**
A. **Not as an employee. Obviously, retained by them a lot, but not as an employee.**
Q. **Right. But not as an employee of the company. Correct?**
A. **Correct.**
Q. **We already touched on this a little bit and I know you testified about this on direct. But Aventis used a variety of marketing messages for Nasacort AQ, didn't it?**
A. **Yes, sure, over the years.**
Q. **We saw some of them in the exhibit that counsel for Aventis put up. I think they were Stays where it's Sprayed, Once Daily Dosing, Prompt Relief, odorlessness. Is that right, Dr. Bell?**
A. **Yes, I recall that, sure.**
Q. **You don't have any evidence that Nasacort AQ was prescribed based on the Stays Where It's Sprayed message specifically, do you?**
A. **As I sit here, I am not aware of documents where they**

have asked physicians how was it that you actually prescribed? Was it because of the Stays Where It's Sprayed message? That may exist. I am not aware of it.

Q. Just so we are clear, as of today, as you sit here, you are not aware of any evidence that any physicians prescribed Nasacort AQ specifically on the basis of the Stays Where It's Sprayed message. Is that correct?

A. It would be correct. Not specifically, again, it's part of the overall positioning of the product that generates sales.

Q. Again, I am trying to focus specifically on the state --

THE COURT: I think he has answered that question.

BY MS. JOHNSON:

Q. You don't have any evidence that Nasacort AQ was prescribed because it's odorless. Correct? And again I am referring to specifically based on that message.

A. Well, I am certainly aware that there are patients that -- patients -- that there is clinical studies that show that some patients prefer the odorless formulation. I am not aware of documentation that says that this physician prescribed Nasacort AQ for this patient because of odorlessness. But that can certainly be the case.

Q. Okay. But you don't have any evidence that those

patient preference studies actually translated into prescriptions for Nasacort AQ. Correct?

A. Again, I am aware that physicians were aware that it was odorless, and presumably that was part of their consideration when making prescribing decisions.

Q. I appreciate that. I am just trying to find out whether you have any direct evidence that a physician prescribed Nasacort AQ specifically on the basis of the odorless message?

A. Nothing specifically, again, that says for this patient I prescribed it for that reason.

Q. Thank you.

And similarly, that would apply basically for any specific marketing message. Is that correct? You don't have any evidence of any particular marketing message causing a physician to prescribe Nasacort AQ?

A. Yes, that would be pretty standard in my experience for pharmaceutical products in general.

Q. Let's take a look at DX-23, please.

MS. JOHNSON: May I approach, Your Honor?

THE COURT: Yes.

BY MS. JOHNSON:

Q. Dr. Bell, you were in the courtroom when Mr. Boghigian testified about this sales training document, DX-334, yesterday. Correct?

A. **Yes, I was.**
Q. **Okay. Mr. Young, if you could please go to Page 22.**
Now, this describes physician perceptions saying all INS's are the same. Did I read that correctly, Dr. Bell?
A. **Yes, you have read it correctly.**
Q. **Again, this is a sales training document. Correct?**
A. **Correct. That's my understanding, yes.**
Q. **And if we could go to Page 29, please, Mr. Young.**
And again, this says, They are all the same. Did I read that correctly, Dr. Bell?
A. **Yes, you have read it correctly.**
Q. **You didn't consider this document in reaching your opinion about Nasacort AQ, did you?**
A. **I don't believe this document was listed on Exhibit B to my report. I don't believe it was part of what I considered, yes.**
Q. **So if it was listed on Exhibit B, then it wouldn't have been something that you considered. Right?**
A. **If it wasn't listed on Exhibit B or otherwise referenced in the report, and I don't think this was.**
Q. **Okay. Let's turn to one of the demonstrative exhibits that counsel for Aventis put up.**
Mr. Young, are you able to put up Plaintiffs' Demo 31.

Now, Dr. Bell, you testified that this is a presentation of financial results. Is that right?
A. Correct.
Q. But you didn't receive this presentation of financial results in this form from Aventis, did you?
A. No. The actual sources of it are as indicated in Schedule 4.1 of my report.
Q. So you had to compile more than one document into this presentation of financial results. Correct?
A. My recollection is that's correct. Again, it's indicated on I believe Schedule 4.1.
Q. Again, these financial results start in the year 2000. Is that right?
A. Correct.
Q. So this chart doesn't tell us anything about whether Nasacort AQ recouped its initial research and development costs. Correct?
A. Correct.
Q. In fact, you don't have any information about whether Nasacort AQ recouped those costs, do you?
A. No, I don't. But it wouldn't be germane to my opinion.
Q. Let's take a look at Plaintiffs' Demo 27, please, Mr. Young.
Now, Dr. Bell, you testified that this chart

shows the dollar sales of Nasacort AQ. Correct?
A. Well, I think it was quite clear, I said according to IMS.
Q. I heard you testify about the IMS and Verispan data. Just so I am clear, IMS data is based on the product's AWP. Right?
A. This particular audit of IMS is, I believe, based on the product's AWP.
Q. And AWP, that stands for average wholesale price, doesn't it, at least to some people?
A. That's a question of considerable interest in the courts right now. In my considered opinion, AWP is a pricing benchmark used in the pharmaceutical industry.
Q. Okay. But in any event, the AWP is the price before discounts and rebates. Correct?
A. AWP may be considered to be a list price. It is certainly before any discounts and rebates.
Q. So it's not the actual sales, net sales data then?
A. That's correct, yes.
Q. And then I also heard you testify that IMS is what you use when you want to compare a product to its competitors, IMS data. Is that correct?
A. Well, that's one of the sources, sure.
Q. Okay. But I don't see any competitors for Nasacort AQ on this chart. You didn't prepare a chart using the

dollar sales for Flonase, did you?
A. I am not sure I understand the question.
Q. Okay. You didn't do a comparison of dollar sales using IMS data for Nasacort AQ to Flonase, did you?
A. The data is in my report. But I didn't do a dollar share calculation. I did a prescription share calculation.
Q. Okay. I am not even talking about, not just dollar share, but just dollars to dollars. You didn't do that comparison, either, did you?
A. Well, it's sitting right there on Schedule 3.1. If you look at 3.1, you will see the Flonase dollars and the Nasacort AQ dollars.
Q. Let's go ahead and do that then.
Mr. Young, can you please pull up PTX-585.
Now, this is a schedule, this is your schedule 3.1 that you just referenced. Correct?
A. Correct.
Q. This shows dollar sales for products in the INS class. Right?
A. Well, again, it shows dollar sales as recorded by IMS in the category which is, which is the intranasal glucocorticosteroids.
Q. Thank you for the clarification.
Let's take a look at 1997. That's the first full year after Nasacort AQ launched. Right?

A. **Yes, that's correct.**
Q. **Mr. Young, are you able to pull that up so we can read it?**
So looking at 1997, which is the box sort of in the upper center of the screen?
A. **I am not exactly sure this is any easier to read. But all right.**
Q. **Can you see it?**
A. **I can see it says 1997.**
Q. **Then do you see the highlighting in the bottom of that box, there is a highlighted number?**
A. **Sure.**
Q. **So according to your schedule, dollar sales for Nasacort AQ were almost 47 million dollars. Right?**
A. **Well, yes. Again, as recorded by IMS.**
Q. **As recorded by IMS, okay. So that was Nasacort AQ in 1997. Let's look at the first full year after Flonase launched. That's 1995. Right?**
A. **I believe so, yes.**
Q. **If we look at the box in the top left of the screen, it looks like dollar sales for Flonase in its first full year of launch were over 94 million dollars. Right?**
A. **Yes.**
Q. **Why don't we take a look at Nasonex. The first full year after Nasonex launched was 1998. Right?**

A. **Can we get rid of the junk, then I could actually read --**

Q. **Sure. If you feel you can read it better without the boxes, absolutely.**

A. **I am just trying to follow the Nasonex line across.**

Q. **Okay.**

A. **I am sorry. The question was, 1998. Yes, that's -- that's much better -- so 1998, I agree. That's the first full year for Nasonex sales.**

Q. **And dollar sales for Nasonex in that year were over 115 million dollars, weren't they?**

A. **That's correct, according to IMS, yes.**

Q. **Now, let's take a look at the year in which Nasacort AQ generated the most dollar sales according to IMS data.**

That would be 2005. Right, Dr. Bell?

So again, 2005 appears to be the year in which Nasacort AQ generated the highest dollar sales according to IMS data. Correct?

A. **Yes, that's correct.**

Q. **And dollar sales for Nasacort AQ in 2005 were about 350 million dollars. Right?**

A. **Right, according to IMS, sure.**

Q. **Let's take a look at the dollar sales for Flonase in that same year, 2005. Dr. Bell, do you see that dollar sales for Flonase in 2005 were over 1.2 billion dollars?**

A. **Sure, yes.**

MS. JOHNSON: Thank you, Mr. Young.

Let's take a look at the Plaintiffs' Demo 28.1, please.

BY MS. JOHNSON:

Q. **Now, Dr. Bell, this graph shows market share of Nasacort AQ according to total prescription. Correct?**

A. **Yes. It shows the Nasacort prescriptions as a share of total in the INS category.**

Q. **Again, we're looking at Nasacort AQ on this graph. We're not looking at any competitors, are we?**

A. **I haven't graphed any of the competitors, no, but the information again is taken from, I think this is one of the Schedule three-point-somethings in my report.**

Q. **But just to continue looking at this chart or this graph for the time being. It looks like Nasacort AQ's peak market share was 14.4 percent in 2004. Is that right?**

A. **Correct.**

Q. **And it looks likes the scale of your graph goes up to about 16 percent. Am I right?**

A. **Sure. It only had to go up to 14.4 to fit it on the page.**

Q. **Exactly. You mentioned one of your schedules has the data for Nasacort AQ's competitors?**

A. **Sure.**

MS. JOHNSON: Let's take a look at that schedule. I think that it is PTX-703. If you could pull that up please, Mr. Young.

BY MS. JOHNSON:

Q. **Now, it sounds like you didn't, yourself, actually do any calculations of the competitors market share, for example, Flonase. Is that right?**

A. **Well, I don't recall sitting down and computing it year by year.**

Q. **Okay. Well, let's take a look at Flonase market share for 2004. Now, 2004, again, that is the year that Nasacort AQ had its peak market share of 14.4 percent. Am I right?**

A. **Correct.**

Q. **Okay. So let's take a look at Flonase for 2004. And I actually calculated this, using your numbers here that you provided. And I took Flonase sales data which I saw to be 15,347,490, and I divided that by the total corticosteroid market of 33,533,932. And, again, this is total prescriptions, not dollars?**

A. **Correct.**

MR. NOE: Your Honor, I'll object to the form of the question.

THE COURT: Overruled.

BY MS. JOHNSON:

Q. **And that's the correct way to do the calculation. Right?**

A. **In terms of coming up with the share of prescriptions, sure. Yes, that is exactly what I did with respect to Nasacort AQ.**

Q. **Okay. Great.**

MS. JOHNSON: Mr. Young, let's go back to Demo 28, please.

BY MS. JOHNSON:

Q. **Now, the number, the market share percent that I got for Flonase in 2004 was 45.8 percent. Does that sound about right based on those numbers?**

A. **It sounds about right.**

Q. **So Flonase being 45.8 percent, that would be just way off your chart there, wouldn't it?**

A. **Well, on this scale, sure. If I wanted to put Flonase on, I'd adjust it but you would end up with Flonase being about three times the share of Nasacort AQ.**

Q. **Okay.**

A. **Some products are more successful than others.**

Q. **Okay. In the end, you can't deny that Nasacort AQ was never the INS market leader, can you?**

A. **Oh, I never said it was the INS market leader. I simply said it was commercially successful from the perspective of nonobviousness.**

Q. **Not only was it not the market leader but it never did better than number three in the class of INS products. Is that right?**

A. **I think that is right. Yes.**

Q. **Okay. Thank you.**

MS. JOHNSON: I have no further questions.

THE COURT: Thank you, counsel.

MR. NOE: Very briefly, Your Honor.

THE COURT: Sure.

MR. NOE: PX-334.

Take that down, please.

Mr. Young, if you could call up 334 and specifically Page 22 which counsel discussed with the witness.

REDIRECT EXAMINATION

BY MR. NOE:

Q. **Dr. Bell, directing your attention to Page 22 of DX-334, do you see at the top where it says: position perceptions? Would you agree that that suggests that is what doctors might think before learning about the attributes of Nasacort AQ?**

A. **It certainly could be.**

MR. NOE: And, Mr. Young, if I could have the very next page of this exhibit.

BY MR. NOE:

Q. **And indeed on the next page of the exhibit appears, do you see where Settipane appears at the top?**
A. **Yes.**
Q. **And then information about the Settipane study?**
A. **Yes.**
Q. **And immediately below that it says: key selling points?**
A. **Yes.**
Q. **So would you agree then that this appears to be information that would be useful in informing physicians about the attributes of Nasacort AQ?**
A. **Sure. This would be the kind of thing that the reps would be trained on so that if they get the response in the physician office that is, oh, gee, I think they're all the same; well, doctor, let me tell you about the Settipane study and what its results were with respect to Nasacort AQ.**
Q. **And, lastly, Dr. Bell, in addition to the pharmaceutical companies that you mentioned earlier, have you also worked with generic manufacturers as well?**
A. **Yes, I have.**

MR. NOE: Thank you. No further questions, Your Honor.

THE COURT: Thank you, doctor.

(Witness excused.)

THE COURT: How many more witnesses do you have,

Mr. Berghoff?

MR. BERGHOFF: Two more.

THE COURT: Let's take a break.

(Recess taken.)

THE COURT: Please be seated.

Counsel, I received your letter. I think the better part of discretion would have been to have left this subject alone given that yesterday it was over in my judgment, but now you raised it again.

The local rule does not reflect my practice. That should be known to Delaware counsel.

MS. PASCALE: We will honor your practice. And I will share --

THE COURT: I know you will honor my practice, but I don't need to have a local rule of my own court recited to me. I know what the local rules are. I don't agree with this rule. I don't practice it in that way.

Once the witness is on the stand and under oath and under examination, the witness is not to be conferred with by counsel. Is that clear?

MS. PASCALE: Understood, Your Honor.

THE COURT: I would have left this alone.

MS. PASCALE: I apologize for any offense, sir.

THE COURT: Okay. Let's go.

MR. BERGHOFF: Your Honor, plaintiffs call,

recall as their next rebuttal witness, Dr. Robert Lochhead.

THE DEPUTY CLERK: Dr. Lochhead, please be reminded you are still under oath. Thank you.

. DR. ROBERT YATES LOCHHEAD, having been previously sworn as a witness, was examined and testified further as follows ...

MR. BERGHOFF: May I approach, Your Honor?

THE COURT: Yes.

(Binder passed forward.)

DIRECT EXAMINATION

BY MR. BERGHOFF:

Q. Good morning, Dr. Lochhead.

A. Good morning.

Q. You testified in our case-in-chief about some testing that you did on Nasacort AQ. Correct?

A. Yes. Yes, I did.

Q. Were you asked to test the setting and sheared viscosity of Beconase AQ and Flonase?

A. Yes, I was asked to test the setting and sheer viscosity of Beconase and Flonase.

Q. And did you do that?

A. I did that, yes.

Q. And in doing your testing on Beconase and Flonase, did you follow the methods described in the patents in suit?

A. Yes, I followed exactly the methods described by the patents in suit for Beconase and Flonase.

Q. **Now, Dr. Lochhead, we've heard mixed in this case of a prior product called Vancenase AQ. Were you able to test that product as well?**

A. **No, I wasn't able to test that product because I understand that that product has been delisted and it is commercially available. I also understand its attempts to get enough product to do Brookfield testing for that were unsuccessful.**

Q. **And how much of a product do you need at a minimum to do the appropriate Brookfield testing set forth in the patents in suit?**

A. **I need a minimum of 500 milliliters.**

MR. BERGHOFF: Let's put up, if we could -- and I believe it's in your binder as well -- Page 9 from PTX-484.

BY MR. BERGHOFF:

Q. **Dr. Lochhead, do you see that?**

A. **Yes.**

Q. **Could you tell us what it is we're looking at? What is this a page from?**

A. **This is a page from the lab book that I recorded my testing results in with respect to this case.**

Q. **And is this a standard-bound laboratory notebook or something else?**

A. **It's a standard-bound laboratory notebook.**

Q. **And does this page reflect the results of your viscosity testing of Flonase?**

A. **Yes, it does.**

MR. BERGHOFF: And could we perhaps look at --

BY MR. BERGHOFF:

Q. **And do you have a laser pointer with you?**

A. **Yes.**

Q. **Perhaps you could tell us what your results were when you tested Flonase?**

A. **Well, here, I'm testing Flonase and I find that the viscosity of the setting viscosity is in the range of 680 to 720. That is my first result, 720.**

And after shaking, the sheared viscosity is 307 to 375. That is my first result, 307. And that is after shaking, according to the method defined in the patent, the Burrell wrist action shaker.

Q. **And how long did you shake the Flonase in this test?**

A. **Five minutes, as specified by the patent.**

Q. **At what speed?**

A. **At full speed.**

Q. **And just so the record is clear, you were directing us to the numbers under the heading Viscosity (CPS)?**

A. **Yes, I was.**

MR. BERGHOFF: Let's go to Page 8 of this exhibit.

BY MR. BERGHOFF:

Q. And does this page from PTX-484 reflect -- well, what does that page reflect?

A. This shows my testing, my viscosity testing for Beconase.

Q. And what were the results?

A. The results here is my setting viscosity. And then, on the undisturbed sample, 816 centipoises. Going down, about the third time to 720 centipoises.

And 358 centipoises to 376 centipoises for the sheared viscosity after shaking in the same way.

Q. And, again, you were referring to the numbers on this page under the heading: Viscosity (CPS)?

A. Yes, I was.

MR. BERGHOFF: Could we put up Plaintiffs' Demonstrative Exhibit 66.2, please?

BY MR. BERGHOFF:

Q. Could you describe what is shown on this exhibit on the bottom two lines? I don't want to go over what we've already heard in the case-in-chief, just the bottom two lines on this.

A. The bottom two lines summarize my data, my viscosity test data for Beconase AQ and Flonase. And they show that the sheared viscosity in both cases exceeds the limit of 50-to-200 centipoises as specified by the patents.

Q. **And how about the setting viscosity with respect to the range defined in the patents?**

A. **The setting viscosity, with the exception of one which is slightly out, the setting viscosity falls within the range of 400-to-800 centipoises as specified by the patents.**

MR. BERGHOFF: Let's put up Plaintiffs' Demonstrative Exhibit 66.1.

BY MR. BERGHOFF:

Q. **And now, if you could just describe for us the top two lines of this chart, referencing Beconase AQ and Flonase.**

A. **This is a summary of my results, my viscosity testing. And you can see that here we've got the setting viscosity range of 400-to-800 centipoises and Beconase AQ falls within that setting viscosity range, as does Flonase.**

Here, we have the shear viscosity range for the patent, 50-to-200 centipoise; and clearly Beconase AQ and Flonase fall outside, greater than the top end of that range, for the sheer viscosity.

Q. **Thank you, Dr. Lochhead.**

Now, what relationship, if any, does your testing of Nasacort AQ that you described for us in your testimony originally in the case-in-chief, what relationship, if any, does that have to your testing of

Flonase and Beconase AQ?

A. **Well, I know that Nasacort AQ is an embodiment of the patents-in-suit and so this acted as a control to verify that indeed Nasacort AQ falls within the specified range specified by the patents. So this is the control. I have confidence in my numbers and it gives me confidence that Beconase and Flonase are, in fact, outside of the range specified by the patents.**

Q. **Is it usual to have a control in an experiment such as this, Dr. Lochhead?**

A. **Oh, yes. I always try to put in controls.**

MR. BERGHOFF: No further questions, Your Honor.

THE COURT: You may cross-examine.

MR. HURST: I apologize, Your Honor. It's shorter than I expected so I have to find the part of the examination.

THE COURT: Sure. I understand.

CROSS-EXAMINATION

BY MR. HURST:

Q. **Good morning, Dr. Lochhead.**

A. **Hello again, Mr. Hurst.**

MR. HURST: Can you put up, please, Mr. Young, Defendants' Demonstrative Exhibit 35?

BY MR. HURST:

Q. **Just to help us talk through this, Dr. Lochhead.**

This depicts the comparison between your results and Dr. Klingenberg's results; correct?

A. (No verbal response.)

Q. Does it accurately predict those results -- you tested Flonase to come within the claimed setting viscosity. Is that correct?

A. I believe this shows Dr. Klingenberg's results and my results, yes.

Q. And the only difference that you and he got with respect to Flonase's viscosity was with respect to the sheer viscosity. Correct? You found Flonase to be outside the range and Dr. Klingenberg found Flonase to be within the range. Correct?

A. Yes, I found Flonase to be outside the range but Dr. Klingenberg testified that I think that that Flonase viscosity he tested was not a true viscosity.

Q. Right. Now, with respect to the testing that both you and Dr. Klingenberg did, you were both working with five lines in the patent that described the testing. Correct?

A. I can't remember the precise five lines but it was where the lines were in the patent, but I also considered the Brookfield viscosity --

Q. Right.

A. -- thixotropic materials.

Q. And the patent doesn't tell you how much, for

instance, how full to fill the container of the shaker for the Burrell shaker, does it?

A. Well, the Brookfield viscosity tells you 500 mils, a minimum of 500 mils and a minimum size of 600-mil container. But, no, the patent doesn't specify how full.

Q. Dr. Klingenberg ran some experimentation to try to figure exactly how full to make the container. Do you remember hearing that testimony yesterday?

A. That's what he testified to.

Q. Before you did your testing, you didn't do any experimentation? You went straight to the testing. Is that true?

A. Of course, because I had the protocol, and I wanted to -- I couldn't deviate from that protocol. I went straight and made the measurement.

Q. That protocol that you prepared -- can we go to that? It's Defendant's Exhibit 363. This is the -- it's part of your expert report. Correct?

A. I think this is part of my first expert report, yes.

Q. Now, the patent has five lines of description, as we discussed. Correct?

A. If you say so.

Q. My apologies. A few lines. Correct?

A. It has a few lines in the specification of the patent, yes.

Q. **Your protocol spans eight pages. Is that right? Approximately?**

A. **That's correct, but, of course, the patent also specifies Brookfield LVT Viscometer. So I bring in information from the Brookfield --**

Q. **For now, I just wanted to ask whether, is it true that your protocol spans eight pages, approximately?**

A. **I think so.**

Q. **This isn't a standard protocol for viscosity testing. It's something you made up special for this case. Correct?**

A. **The Brookfield portion is standard. My knowledge of thixotropic is standard. What I took from the patent, of course, is special for this case.**

Q. **Your deposition, Page 85, please. Did you answer this question in this way at your deposition, sir:**

"Well, this isn't a standard protocol. This is a protocol you made especially for this case. Right?

"Answer: Yes."

Did you give that answer to that question?

A. **Yes.**

Q. **Now, in making up this special protocol, am I also correct that it involved about ten hours of meetings with counsel to prepare the protocol? Is that true?**

A. **Up to ten hours, yes.**

Q. **And typically, when you prepare experimental**

protocols in your laboratory, you don't meet with lawyers to do so. Is that true?

A. **Yes. Typically, I don't.**

Q. **And in this case, when you make a protocol for experimentation in your laboratory, I take it you typically draft the protocol yourself or have an assistant draft it on your behalf. Correct?**

A. **That depends. Usually, if I am developing a protocol, I will meet with the people I am doing the method for and we will be able to discuss the protocol sometimes at length.**

Q. **In this particular case the lawyers actually did the physical draft of the protocol for you. Correct?**

A. **After I had discussed and told them what I wanted in the protocol, yes, they drafted, they put it to paper.**

Q. **But you would agree with me, typically, when you are conducting experimentations for specification purposes, that lawyers don't draft your protocols?**

A. **Lawyers don't, but clients sometimes do.**

Q. **When you did your testing -- can we go back up, please, to Demonstrative Exhibit 35. You did your testing and you found Nasacort was outside the range for shear viscosity. Correct?**

A. **That's correct.**

Q. **Are you aware of any other testing done on Flonase in**

connection with this case other than the testing that you did for Aventis?

A. No.

Q. Who selected this Flonase batch for testing? Was it you or was it the Aventis legal team?

A. It was sent to me, as far as I know, straight from Flonase, but from GlaxoSmithKline -- GlaxoSmithKline in a box. But it was sent by -- counsel had it sent to me.

Q. Counsel had it sent to you. Right?

A. Yes.

Q. Regardless of whether Flonase actually falls inside or outside the claimed shear viscosity, you would agree, wouldn't you, that Flonase has a suitable viscosity profile for a nasal spray?

MR. BERGHOFF: Your Honor, we are clearly outside the scope here.

THE COURT: I think we are.

MR. HURST: If it is clear that Mr. -- I am sorry, apologies -- if it is clear that Dr. Lochhead is not offering any opinions on obviousness at all, then we will be outside. But I think the examination was for the purpose of obviousness.

THE COURT: I didn't take it as such.

MR. BERGHOFF: It was to put the testing into evidence, Your Honor. There was no questioning on

obviousness.

THE COURT: Do you still maintain?

MR. HURST: I will, I guess --

THE COURT: I didn't take the import of his testimony to be as you describe it.

MR. HURST: Let me try again. I think I will do better this time, at least I hope.

The purpose of the testimony is that Flonase is different from the claimed invention. That is the purpose of Dr. Lochhead's testimony. I am now about to show, hopefully, that it is not a difference that matters in any way, shape or form.

THE COURT: I will permit you to do that.

MR. HURST: Thank you.

BY MR. HURST:

Q. Now, regardless --

THE COURT: Keeping in mind the scope.

MR. HURST: It will be limited, Your Honor.

BY MR. HURST:

Q. Dr. Lochhead, is this, in fact, Flonase is, in fact, according to your testing, outside the shear range, but that's not a difference that actually has any practical impact as far as you know. Correct?

A. I don't know that it's got any difference in practical impact, because I was testing viscosity, not the

effectiveness as a nasal spray.

Q. For instance, you know that Flonase has a suitable viscosity profile for a nasal spray. Correct?

MR. BERGHOFF: Your Honor, now we are beyond what he says he is comfortable with in his expertise.

THE COURT: I am going to sustain that.

BY MR. HURST:

Q. You are aware of no evidence suggesting that the difference in viscosity level for Flonase has any impact on frontal sinus deposit, are you?

A. No, I am not aware of that.

THE COURT: He has answered it. I think he said no.

BY MR. HURST:

Q. The answer is no?

A. No.

MR. HURST: Your Honor, I have no further questions.

THE COURT: Mr. Berghoff.

MR. BERGHOFF: No questions, Your Honor.

THE COURT: Thank you, Doctor.

THE WITNESS: Thank you.

(Witness excused.)

MR. RICH: Your Honor, for our next witness we would like --

THE COURT: Hopefully your last one.

MR. RICH: For our last witness, next and last witness, all at once, we would like to recall Dr. Eli Meltzer.

THE COURT: All right.

... ELI MELTZER, having been previously sworn as a witness, was examined and testified further as follows ...

MR. RICH: Your Honor, may I approach?

THE COURT: Yes, you may.

DIRECT EXAMINATION

BY MR. RICH:

Q. **Hello again, Dr. Meltzer.**

A. **Hi.**

Q. **I would like to start by talking about some intranasal steroid sprays that I think we have heard enough about. But maybe just a couple more details.**

Now, starting with Beconase AQ and Vancenase AQ, in a couple words, what were they?

A. **Beconase AQ, beclomethasone dipropionate was the molecule, and they were placed in an aqueous suspension.**

Q. **What was the preservative system in Beconase AQ and Vancenase AQ?**

A. **They both had benzalkonium chloride and phenylethyl alcohol.**

Q. **Do you believe phenylethyl alcohol is odorless?**

A. **No.**
Q. **According to the Court's definition, do you believe phenylethyl alcohol is odorless?**
A. **According to the Court's terms, I do not believe Beconase AQ and Vancenase AQ are odorless.**
Q. **And then Flonase, up on the right at the top, what's Flonase?**
A. **Fluticasone propionate is another intranasal corticosteroid in an aqueous suspension.**
Q. **What was the preservative system in Flonase?**
A. **Benzalkonium chloride and phenylethyl alcohol.**
Q. **Again, phenylethyl alcohol is not odorless. Correct?**
A. **Correct.**
Q. **So do you have an opinion as to whether Flonase is odorless?**
A. **I believe Flonase is not odorless.**
Q. **On the second row, the third one over, is a product called Tri-Nasal. Are you familiar with Tri-Nasal?**
A. **I am.**
Q. **What was Tri-Nasal?**
A. **Tri-Nasal is a preparation that was developed, now not on the market, of triamcinolone acetonide. It was a solution rather than a suspension, a co-solvent solution with polyethylene and propylene glycol.**
Q. **When was Tri-Nasal developed?**

A. **Around 2000, I believe.**
Q. **Was that before or after Nasacort AQ?**
A. **It was after.**
Q. **Did that have phenylethyl alcohol?**
A. **It did not.**
Q. **Why not?**
A. **I believe it related to a conversation that I was part of. I was a consultant for Muro. I knew the head of their consultancy group, Dr. Elliott Ellis, who was my chief when I was in training, and the president George Barakas (phonetic), and they brought a number of advisors together to talk about their proposed product. And one of the conversations included discussions of excipients. And there was a recommendation not to include phenylethyl alcohol.**
Q. **Why was that recommendation not to including phenylethyl alcohol made?**
A. **Because there were patients that we were seeing that preferred not to have a scent in it.**
Q. **And you said that Tri-Nasal is no longer on the market. Do you know why it's no longer on the market?**
A. **I think for several reasons. One, it had a really burning quality to it. The propylene and polyethylene glycol was quite stinging and patients didn't like it.**
The delivery system was problematic. It never came out in a general spray. It actually came out more in a

spritz that was problematic.

Thirdly, there was a, apparently, time when it was in transit that it would be cold, that it would lose its solubility. So it precipitated from solution and therefore it wasn't stable. I think the FDA required it to be withdrawn.

Q. Now, you have already told us that Beconase AQ, Vancenase AQ, and Flonase are not odorless. And I would like to get into the basis of that opinion, if I could.

Do you have any personal experience that informs that opinion?

A. Well, we certainly have been using intranasal corticosteroids in our practice for decades. And when we see patients, whether it's for asthma or for rhinitis, we always demonstrate the actuation of the delivery system so that the patients are familiar with it. Particularly for children, I think it gives them some comfort to see how it is and feel it. So we spray it on their chin, we will spray it in their nose. We do the same thing with adults, to teach them how to aim it.

So we have actuated many, many canisters and units into the air. And patients often comment on the phenylethyl alcohol that was part of some of the other products, the Beconase AQ, Vancenase AQ, Flonase, that there is that rosy smell. It's pretty obvious.

Q. **Do you have any experience with whether patients have believed it to be uncomfortable?**

A. **Yes. I think that there are patients who don't like it. They don't always say that one time is problematic. But there are many patients who say they don't want to have that smell all the time. It's like a perfume you don't like.**

If you have to use it every day -- and it is important they use their medicine every day. I mentioned a couple days ago how critical it is for patients to sustain the use of their anti-inflammatories so they don't continue having symptoms. We need to make sure they don't have anything that would dissuade them from doing that. And I have had patients who really find it undesirable.

I remember this one patient I commented on before, who actually said he hated to use it because the rosy smell always reminded him of funerals.

Q. **Does phenylethyl alcohol have any characteristics as an alcohol that are seen as uncomfortable?**

A. **Alcohol is drying. If you put it on your skin, you will notice it is drying. If you put it in your nose, it can be somewhat drying as well. It is that same sensation, if you have been in an airplane or in cold air, you get sort of dried membranes. Patients who already have hyper-responsive airways don't like that dryness. It makes**

them uncomfortable. I think phenylethyl alcohol as an alcohol is problematic because of the drying process.

Q. Hyper-responsiveness, that was something you mentioned a couple days ago in relation to symptoms of the late-phase reaction, I believe, of allergic reaction?

A. Chronic inflammation creates an airway that's inflamed and unstable. So it takes very little allergin or irritants to stimulate. That is true in the allergic people. As part of the groups that we see with rhinopathies there are patients that have what we call non-allergic rhinitis. They have an airway that doesn't accept very well the changes of weather or irritants, normal levels of pain, perfume, hair spray, tobacco smoke, whatever it is. That bothers them and causes them increased congestion and nasal discharge.

So we prefer not to have -- as a matter of fact, we have an office policy that says, to our employees, don't wear perfume because there are patients who it bothers.

So low-grade irritants are problematic for people with non-allergic rhinitis.

Q. We have heard in the Court, but just to be clear, what's the scent in phenylethyl alcohol that causes this discomfort?

A. It's described as a rose scent, smell of a rose.

Q. Now, Dr. MacKay mentioned in his testimony that he

was aware of certain studies, certain articles that relate to the odor of various of these steroid spray products. Are you familiar with any studies of sensory attributes?

A. I am.

Q. Could you tell us about them?

A. I would be happy to. What I would like to do is present to you some studies that have been done on this specific subject. I will spend a little more time on the first couple and kind of review the others relatively rapidly.

Eric, if I could have that first one.

This is a United States study that was published in 1999. I would like to point that the blue is really the one that is the non-phenylethyl alcohol. In this case it's Nasacort AQ. Then the other two are the ones with phenylethyl alcohol, Beconase and Flonase.

If we could have the next slide, I would like to, there should be one that, in fact, is the grade-out -- Eric, in between -- thank you -- of the three attributes I would alike to focus on of odor, taste, and irritation.

You can see in this Gerson study that when you look at odor strength, which is important because as I said, people with allergic rhinitis and non-allergic rhinitis, the irritants of an odor can bother them, there was a statistically greater lessening of the odor strength than

those that didn't have the phenylethyl alcohol, in this case Nasacort, compared to the Beconase and Flonase.

In fact, it was perceived as a less problematic odor. They liked it, on a scale of zero to five, they liked it better. It didn't seem to bother them as much when it didn't have the odor.

So the odor is clearly better for the patients. And these were some 95 patients who had what we call a crossover study to say that they experienced the Nasacort, they experienced the Beconase, they experienced the Flonase. Then each time after each one of those, they made a rating as to how it was for them in terms of the odor.

Similarly, in terms of taste, they liked the taste better in the one without phenylethyl alcohol compared to the two that had phenylethyl alcohol.

This was immediately following the spray in the nose.

They also felt that it was more comfortable, less irritating, and there was a greater amount of moistness immediately.

Overall liking was clearly better in the ones that didn't have the phenylethyl alcohol. And that's the Gerson study.

Q. Where was that study published?

A. It says at the bottom Journal of Sensory Studies,

1999.

The next study was done in Europe. Klaus Bachert lives in Belgium. This was a multi-country study that had again some 90-ish patients, a number of sensory attributes.

We see again in blue, the triamcinolone acetonide compared this time to Flonase and the old Nasonex. The old Nasonex had in it phenylethyl alcohol.

We see that if you look -- if we could have the next slide, Eric -- those same three attributes, the odor strength was lowest in the ones without phenylethyl alcohol. The perception that they liked the odor, that is to say it didn't have an odor, was best in the one without phenylethyl alcohol compared to the other two. The tasting was best with the one that didn't have phenylethyl alcohol. And again, the issues of irritation or comfort, best in the triamcinolone acetonide. Lowest irritation, most moist-feeling.

When the patients two minutes after it was sprayed were asked about aftertaste and about amount of irritation, again, they felt that that was best in the one without phenylethyl alcohol.

If we look at the next slide, it shows kind of an overall. It has two additional aspects. When the patients were asked after each time, that's what we have in

that first report of whether it was a taste problem or odor problem, this is an overall liking. And you can see the one called Nasacort AQ was better than Flonase or the old Nasonex. And they were asked, also, which one would you prefer to be prescribed. And you can see the statistical difference on that.

Then they asked, if you were prescribed that one, are you more likely to comply. The answer was, yes, they are more likely to comply.

Again, to me as a clinician that is critical, because I want to make sure that people -- there is actually something called primary noncompliance where you write the prescription, and the patient never even fills it. This is usually a problem when people get it and they won't continue taking it. And I want to make sure they continue taking it. So those are the first two studies.

Briefly, if I could have the next slide, one by Bill Lumry down in Texas, where he did a study. This was not a crossover study, so the people either had the Nasacort or Beconase AQ. And then at the end of the three weeks of trial they were asked how do you feel about the medicines in different ways. And when that was statistically analyzed, the taste was preferred in the ones without phenylethyl alcohol, namely, the Nasacort, compared to the Beconase beclomethasone propionate. And the same thing for smell.

Next slide.

And that is what we see kind of called out from that particular bar graph.

Next.

And this study was done in Asia. This was a large study. The others were 150 people, 95 people. This was 350 people, Dr. Bunnag from Thailand. And she again compared without phenylethyl alcohol, which is triamcinolone acetonide here on this left column, to Flonase in this middle column, to the old Nasonex on the right column. And the ones I have highlighted are related to odor which you can see is better in the triamcinolone acetonide, taste which is better in the triamcinolone acetonide, amount of irritation and comfort immediately following the nasal spray.

And if we could have the next slide.

And then this aftertaste is better in the triamcinolone acetonide. And the overall liking, you can see the statistical differences compared to the Flonase and the mometasone.

The next slide is interesting again because they asked, after you have done these three different crossovers from A and B and C, which one would you prefer? The one that was preferred the most was the triamcinolone acetonide. And they were 82 percent of the people said if they get the

one they most prefer, they're likely to comply. But if you look on the bottom right-hand side, if they don't get the one that they would prefer, almost 50 percent of the people said they probably wouldn't comply. And that, to me, is a bad outcome for patients.

Q. Well, which one was the most preferred in?

A. The most preferred was the triamcinolone acetonide. The Nasacort AQ.

Q. And which one the least preferred?

A. It was mometasone furoate, the old Nasonex with phenylethyl alcohol.

As a matter of fact, these studies were published around 2003. I served on an advisory board for Schering because they were concerned about the inference that people might not take their medicine, and so they said can we do anything? And we again recommended that they consider taking phenylethyl alcohol out of their product. And they subsequently did.

So the new Nasonex is called unscented Nasonex. You probably have heard Antonio Banderas. He does this little bumblebee: Don't. Take mine. Your nose would be better. No scent.

Anyway, he does this and they always recommend the unscented component of it. You can see we did a study.

If we can see the next slide. This is the last

one I'll present.

It compared the new Nasonex which is here in this maroon color with the Flonase. So it's changed only in that it doesn't have phenylethyl alcohol in it. And as far as after spraying it -- this again was a crossover study -- that people were able to taste both of these. The one with less scent was the one without phenylethyl alcohol. The one with less taste was the one without phenylethyl alcohol. And the patients were describing this on a more satisfied or less satisfied score.

Moisture again was more soothing with the one without phenylethyl alcohol. It didn't have the drying aspect.

And the next slide shows that two minutes after spray, less scent, less taste, more satisfied. It sounds like a beer commercial. And more likely to comply if you get the one that you would like.

And then they were asked: Okay. You have had X and you have had Y, if you compare them, what do you feel about them?

And you can see on last slide.

Overall, they preferred the one without phenylethyl alcohol. The new Nasonex, better scent. That does say no scent. Better taste. Better aftertaste. Less irritating, less irritation to sneeze.

That is kind of the overview of the sensory aspects which I see as sort of integrated: the integration of what people perceive in terms of moisture and smell and taste and irritation.

Q. And I'm not going to try to do the Antonio Banderas imitation. But the advertising for Nasonex, does it now feature this odorless scent-free attribute?

A. It does. It's one of their highlights.

MR. RICH: And I think we may have one of their website pronouncements.

BY MR. RICH:

Q. And I guess if you could just read it for us?

A. It says: Do you prefer a nasal spray with a scent-free formula?

We know that the entire world can't smell like roses, but that doesn't mean that it needs to smell like your nasal allergy medicine either. Nasonex is scent-free, so that's just what you get.

Q. I just wanted to try and summarize. Can you summarize these studies for us in any way?

A. Well, I made sort of a panoramic view of these five studies. And in blue is the ones without phenylethyl alcohol, most of the time being the triamcinolone acetonide. And the last study being the mometasone. And you can see, if you compare odor, the one that is perceived as less liked

or in one case called more bad or less bad is the one with the phenylethyl alcohol.

The same thing is true on taste.

And the same thing is true in terms of discomfort. Sometimes, it's referred to as dry. It's always the one with phenylethyl alcohol. More uncomfortable. Always the one with phenylethyl alcohol. Stinging and burning was the wording. Irritation both immediately and following a couple minutes of evaluation.

So it was a very consistent response. And these are hundreds of people who often compared apples to oranges and found that the one without phenylethyl alcohol was preferred.

Q. And why are these sensory attributes important to you?

A. I think patients come to see me because they don't feel well. And I perceive my responsibility as trying to help them to improve their symptoms, to improve their quality of life. And if I have newer treatments that either are more effective or more safe or more tolerable, then I can serve my patients better. And, in addition, I really appreciate the advances that have been made by scientists and companies that bring to patients better care. It helps me to do my profession and it's very satisfying when patients do feel better.

Q. **Thank you.**

MR. NOE: Your Honor, we have no further questions.

THE COURT: All right. Mr. Gracey, you may cross-examine.

CROSS-EXAMINATION

BY MR. GRACEY:

Q. **Hello again, Dr. Meltzer.**

A. **Mr. Gracey.**

Q. **You just summarized for the Court a number of the so-called patient preference studies. Isn't that right?**

A. **Yes.**

Q. **Okay. And not a single one of those studies are validated. Isn't that true?**

A. **What do you mean by "validated?"**

Q. **Well, actually those were your words that you used in an article. Right? "Validation."**

A. **The questionnaire?**

Q. **Right.**

A. **They're validated questionnaires.**

Q. **Fair enough. I apologize, you are absolutely right. The questionnaires, that we're attempting to valuate various sensory attributes, odor, what have you, those questionnaires weren't validated. Isn't that true?**

A. **Much of what we do in clinical care is not validated,**

but it is a very well controlled study because each patient was asked exactly the same question, on the same rating scale in a crossover design in most of those studies, so that is a pretty good clinical trial.

Q. Didn't you, yourself say that non-validated questionnaires actually limit, limit one's confidence in interpreting the results of the findings?

A. They limit if it's not a standardized system. But most of what we do -- and I ask you as a patient, "how are you today?" That is not a validated question. In all the clinical trials, when we rate people's symptoms of mild, moderate, severe, that is their experience. It's not a validated system. So there are many things we do in clinical care that have not gone through the rigors of statistical assessment or reproducibility and reliability and validity, which is really a very vigorous symptom. And we don't have that for almost ever we do from history to physical examination and clinical care.

Q. I appreciate that. Let me just ask it again and see if I can get it again. The non-validated questionnaires actually limit one's confidence in interpreting the findings of these questionnaires or these studies. Isn't that true?

A. These are the only studies that exist, to my knowledge, and they are limited by the fact that before the questionnaires were developed, they didn't go through the

rigor of making a validated questionnaire.

MR. GRACEY: If we could put up, I believe it's DX-90 on the screen, please.

And I believe DX-90, not 91. Thank you.

BY MR. GRACEY:

Q. All right. Dr. Meltzer, this is one of your papers; true?

A. It seems to have my name on it.

Q. It's entitled: Development of Questionnaires to Measure Patient Preferences For Intranasal Corticosteroids in Patients With Allergic Rhinitis. Did I get the title right?

A. Yes.

Q. All right. And you actually wrote this article with Mr., or, excuse me, Dr. Georges who we heard from at the outset of the case. Right?

A. Correct.

Q. All right. Now, what year did you publish this study?

A. I can't read it but it looks like 2005, which would be after all of the clinical trials that were done before that that I just presented and there has never been done any one since then.

Q. Yes, you actually anticipated my question. So let me ask you to direct your attention --

MR. GRACEY: And, Jeremy, if you could bring up and highlight the bottom the last sentence of the page that carries over. It starts "although." Yes.

Thank you. He brought up the next page, too.

BY MR. GRACEY:

Q. **Although these questionnaires -- now, I believe you are specifically referring to the questionnaires, the studies that you were discussing here. Although these questionnaires were able to detect differences in preferences among INSs -- again, that is short for intranasal steroids. Right?**

A. **Correct.**

Q. **The process by which they were developed or their psychometric property (e.g., reliability and validity) have not been reported, limiting confidence in interpreting study findings.**

That is what you wrote. Correct?

A. **Correct.**

Q. **In fact, you were referring to, for instance, the Bechert study?**

A. **Bachert.**

Q. **Bachert. You are referring specifically to the Bachert study. Right?**

A. **Yes.**

Q. **All right. So many of these studies that you**

discussed are actually just single dose studies. Right?

A. **Correct.**

Q. **And those are just where a patient takes one puff of one product. Right?**

A. **They take, on a given moment in time, a spray. Then we wait a certain period of time, depending upon the type of molecule. And then on another occasion, sometimes a day later, they'll take the other product.**

Q. **Right.**

A. **And they rate each time, the properties, the attribute after each one. And then often at the very end, since it's a crossover study, we'll ask them again to compare the apples and oranges.**

Q. **And those single dose studies aren't as reliable as a multidose study. Right?**

A. **No, I wouldn't characterize that. They're reliable for the information they give you and the attributes are the attributes. Those attributes typically don't change over time.**

Q. **Okay. You actually ended with a little bit about compliance. And isn't it true that compliance with therapy in clinical practice cannot be guaranteed on the basis of a single doze study? Isn't that right?**

A. **Of course.**

Q. **Okay. So the conclusions that the authors were**

attempting to make, and I'll emphasize "attempting," actually they can't guarantee any compliance based on any of these studies they saw with respect to whether one product is preferred over the other?

A. **That's correct. They need to have follow-up evaluations. But we do know certain things about human behavior. If you make something uncomfortable, people -- you know, if you shock somebody every time they do something, they typically don't keep on doing it. And so if you give someone a reward, they typically are more likely reinforced to continue doing it. So we try to find things that accentuate the positive.**

Q. **Okay. In fact, some of these studies go back as far as 1999. Right?**

A. **Yes.**

Q. **And yet there has been -- that is almost a decade. There has been no follow-up since then for any of these studies. Isn't that right?**

A. **To my knowledge.**

Q. **Right. Okay.**

MR. GRACEY: You can put it down.

BY MR. GRACEY:

Q. **Mr. Rich put up a demonstrative that showed a number of prior art products and included Afrin, for instance, and a whole list of products. Right?**

MR. RICH: Your Honor, I believe he is misrepresenting the demonstrative.

THE COURT: I'm sorry, counsel. I can't hear you.

MR. RICH: I believe he is misrepresenting the demonstrative. I can give him a copy.

MR. GRACEY: I withdraw. He is right. I was referring to a different demonstrative. I'm okay with that.

BY MR. GRACEY:

Q. **Let me ask you this: Isn't it true that a pharmaceutical formulator would look, for instance, to Afrin when they're designing formulations for an aqueous nasal spray?**

MR. RICH: Your Honor, this is well beyond the scope.

THE COURT: Sustained. Sustained.

MR. GRACEY: Okay.

BY MR. GRACEY:

Q. **Now, Dr. Meltzer, you were here in the courtroom yesterday. Right?**

A. **I was.**

Q. **And you were here when --**

(Counsel confer.)

MR. GRACEY: Could I get a sidebar?

THE COURT: Sure.

(The following took place at sidebar.)

THE COURT: Yes, Mr. Gracey.

MR. GRACEY: Your Honor, I was going to ask Dr. Meltzer about the slide that was shown to Dr. Kaliner on the CT scan because Dr. Meltzer I believe is going to state that there is no frontal sinus on the CT scan. I would ask for a little bit of the Court's indulgence and leeway as we don't have an opportunity to put on any rebuttal case for our enablement case. I could do this or I could bring a witness and put him on the stand.

THE COURT: I'll let you do that.

MR. GRACEY: Okay.

(End of sidebar conference.)

BY MR. GRACEY:

Q. Okay. Dr. Meltzer, you were here when Dr. Kaliner testified yesterday. Correct?

A. Yes.

Q. All right. And you were here when they put up --

MR. GRACEY: Well, let's put up P Demo 7.1, Jeremy.

BY MR. GRACEY:

Q. Okay. And Dr. Kaliner was shown this slide and he testified that this indicated the frontal sinus. But you know that the frontal sinus is nowhere on the CT scan, don't you?

A. I can't tell, because I don't have all the CT images, exactly where the frontal sinus is in this individual.
Q. I appreciate that. But in this particular CT scan, it's not shown, is it?
A. Without context of all the slices, I don't know 100 percent that this frontal sinus is not on there. I'd have to see the other slices.
Q. Can I ask you what that is right there?
A. I'm sorry. I didn't see it.
MR. RICH: (Standing up to object.)
THE COURT: Overruled. I note the objection.
MR. RICH: He just -- okay.
THE COURT: I ruled at sidebar. I'm going to permit a small amount. Go ahead. Let me hear it.
MR. RICH: The witness already indicated he doesn't know, one way or the other.
THE COURT: I'm going to let him question further on it.
MR. GRACEY: Thank you, Your Honor.
BY MR. GRACEY:
Q. I was asking about this region right here, Dr. Meltzer.
A. It appears to be one of the sinuses.
Q. Okay. And which sinus is that? Is that the frontal sinus?

A. **I can't say unless I have seen all the slices related to this patient.**

Q. **Isn't that the ethmoid sinus?**

A. **It certainly could be.**

Q. **And what is this here?**

A. **It appears to be one of the sinuses as well.**

Q. **You have seen CT scans before. Right?**

A. **I have.**

Q. **And you have seen CT -- okay. What is this here, the black there?**

A. **It appears to be the middle meatus area.**

Q. **All right. And what is this right here, this black right in here?**

A. **It appears to be between the septum and the middle turbinate.**

Q. **Okay. And is this the frontal sinus up here?**

A. **That's where it's usually located.**

Q. **Is this the actual frontal sinus?**

A. **I don't see it there.**

Q. **This is actually the frontal lobe of the brain; right?**

A. **More likely.**

Q. **What is this right here?**

A. **It appears to be the roof of the nose.**

Q. **And --**

A. **Do I get a grade on this test?**
Q. **Dr. MacKay is grading you.**
A. **I have no doubt. I have no doubt. I'm surprised Dr. Siegel is not here as well.**
Q. **He wanted to be but he had to catch a flight. This is the middle turbinate. Right?**
A. **It appears to be.**
Q. **And this here is the interior turbinate?**
A. **It appears to be.**
Q. **And this here is the maxillary sinus?**
A. **It appears to be.**
Q. **I'll just ask one last time: The frontal sinus is nowhere shown on this CT scan, is it?**
A. **I'd feel more secure if I saw all slices.**
Q. **Okay. Can you not answer that directly? I mean can you point to the frontal sinus anywhere on this CT scan for me?**
A. **I don't see the frontal sinus.**

MR. GRACEY: Thank you. That's all the questions I have.

THE COURT: You may redirect, counsel.

REDIRECT EXAMINATION

BY MR. RICH:
Q. **Returning to the exhibit we've just looked at, do you know if the frontal sinus is shown or not on this figure?**

A. **I don't know 100 percent.**
Q. **And do you know whose slides these were?**
A. **I do not know.**
Q. **And do you know where in the nose this was taken?**
A. **I do not know the level of the cut.**
Q. **So I know he has asked you what you think interpretively. Would you make a diagnosis of whether that was the frontal sinus or not based on only this image of the CT scan without having additional information?**
A. **I'd like to see the entire CT scan before I make an interpretation. I'd also like to have the radiologist who looks at them a lot more often than I do. This is not my skill level that I rely on, so ...**
THE COURT: Dr. Kaliner didn't seem similarly constrained. Are you surprised by that?
THE WITNESS: Dr. Kaliner is very -- He's the Past President of the American Academy, of the World Allergy --
THE COURT: Hold on. Sorry. You have to let me talk.
I'm not questioning the doctor's qualification. I'm just making an observation. Are you surprised by his apparent ability to identify the area in question on this scale?
THE WITNESS: He may have more experience than I

do in reading CTs.

THE COURT: Okay. That's fair.

BY MR. RICH:

Q. If fact, you were here in the courtroom when he talked about his experience observing in the nose. Right?

A. Right. He does rhinoscopy. I do not.

Q. And he said he did it pretty much every day.

A. He did.

THE COURT: I know that. Okay.

BY MR. RICH:

Q. You were asked questions about validation of study questionnaires. These surveys, how did they relate to your personal experience? That is, how does the results shown in those studies compare to your personal experience as a physician?

A. Well, they're very consistent. We often will give people different options when we have them to try X or to try Y or to try Z. And this is very consistent with what our experience is in terms of usual preferences and usual complaints and usual lack of complaints. So I think they are consistent.

But you have to remember I treat one patient at a time. I'm not doing 364 people in a crossover study in an organized system. So, yes, my usual one-at-a-time patient does report in a similar fashion but that is an anecdote,

not a well designed trial.
Q. Well, you are also asked about whether compliance was guaranteed from asking patients whether they would comply. Do you remember that question?
A. I do.
Q. Are you familiar with the Allergies in America study?
A. I'm very familiar with it.
Q. How so?
A. I was one of the authors for it.
Q. And what did that study involve?
A. Well, there were actually two Allergies in America surveys. There was one in 2006, which was of some 30,000 homes looking and culling out 2,500 adults who had nasal allergies; and then the one in 2007, looking again at some 30,000 homes and culling out 500 children with allergies and 500 children without allergies.
Q. What were the results in relation to sensory attributes and compliance by patient?
A. Sensory attributes were clearly important. They talked about, in both of the adult and pediatric study, reasons why people do not continue taking their medicine, why they stop taking their medicine. And somewhere between 20 and 25 percent of the people reported they stopped taking their medicine related to attributes such as taste, smell, runoff, rundown, irritation, local tolerability issues. So

it's an important part.

As I mentioned earlier, for me that is a critical issue because with any inflammation process, you need to make sure you keep water on the fire. Otherwise, the patient becomes symptomatic. So if they take the treatment intermittently, sporadically, they're going to be much more symptomatic. And that is that symptomatic problem will manifest itself in their life. They won't sleep well. They won't feel well. They won't perform well at work or at school. So compliance to a treatment regimen is really what we, in chronic care, be it diabetes or seizure disorders or arthritis or respiratory medicine, we need to have people sustain their care.

Q. And just to be clear, was this prospective, them saying I wouldn't do it because of this, I wouldn't take the medication because of this? Or was it retrospective, I stopped taking the medication because of this?

A. It was retrospective. They didn't do a prospective study where they took 2,500 people and said take it and see how you do.

I don't know any good prospective studies at all. If anybody would like to fund it, I'd be happy to help out. It would be my pleasure. But that was a retrospective study.

MR. RICH: Thank you.

Your Honor, I have nothing further.

THE COURT: Thank you, doctor. Great time to make a pitch.

(Laughter.)

MR. RICH: Your Honor, we have no further witnesses but we would like to move the exhibits from cross-examination into evidence.

THE COURT: Okay. Do you want to nominate those exhibits or identify them in some way?

MR. RICH: We would.

THE COURT: Okay. And while you are doing that, are these exhibits that have heretofore not been previously ruled upon?

MR. RICH: They have not previously been ruled upon, Your Honor.

THE COURT: Okay. Have counsel had a chance to discuss this?

MR. RICH: No, Your Honor.

THE COURT: Would you like to take an opportunity to review the list.

MR. RICH: Absolutely.

THE COURT: Okay. While we're doing that, perhaps other counsel can attend a small matter. Mr. Berghoff or Ms. Rurka, you can take care of the list.

I have a letter from Mr. David Wilkes of the

Reed Smith firm. I don't think it's problematic but he represents Schering Plough. I don't believe that there is a concern but it addresses confidential information that was produced pursuant to the Barr subpoena. And I don't believe any of Schering Plough's confidential information has been displayed during this trial. Is that correct?

MR. BERGHOFF: It has not been.

MR. HURST: That is my understanding.

THE COURT: So that is confirmed for the record by both parties and we can allay Mr. Wilkes' concern. He had just asked if that were going it be -- it's a little late, but that if we were going to do that, that we seal the courtroom. Whether I would have acceded to that or not, I don't know, but it's sort of a moot point. I just wanted to confirm that.

Okay.

MR. HURST: Your Honor, I won't have any objections. I don't even need to review them.

One of the things we did not do throughout the trial is move in our exhibits as we went along.

THE COURT: Well, your exhibits are in.

MR. HURST: Okay. That was my understanding. Thank you, Your Honor.

THE COURT: Yes.

MR. RICH: Your Honor, if I might approach with

the exhibits?

THE COURT: Sure.

Okay. So let the record reflect that counsel has just -- do you want to announce the numbers?

MR. RICH: If I could.

THE COURT: Just so it is clear for the record what's in there.

MR. RICH: Thank you very much, Your Honor.

Exhibit 393 is an article by Gerson and others.

Exhibit 758 is an excerpt from the Physician's Desk Reference of 1995.

Exhibit 759 is an excerpt from the Supplement A to the Physician's Desk Reference of 1995.

Exhibit 760 is an excerpt from the 1996 Physician's Desk Reference.

Exhibit 1057 is a document entitled Measuring The 'Setting' And 'Shear' Viscosities Of Dispersions Prepared By Daniel J. Klingenberg.

Exhibit 1058 is a publication by Jog and others entitled How Frequent Are Sensory Sinus Ostia?

Exhibit 1059 is a publication by Dr. Naclerio and others, entitled Patient And Physician Perspectives On The Attributes Of Nasal Allergy Medications.

I was going the wrong way with titles, there.

Exhibit 1060 is an article by Skoner and others

entitled The Effects Of Intranasal Triamcinolone Acetonide And Intranasal Fluticasone Propionate On Short-Term Bone Growth And HPA Axis In Children With Allergic Rhinitis.

Exhibit 1061 is an article by Wilson and others entitled Effects Of Repeated Once Daily Dosing Of Three Intranasal Corticosteroids On Basal And Dynamic Measures Of Hypothalamic-Pituitary-Adrenal-Axis Activity.

And we could provide a copy to the court reporter for spelling, if you would alike.

Exhibit 1062 is an article by Dondeti and others entitled In Vivo Evaluation Of Spray Formulations Of Human Insulin For Nasal Delivery.

Exhibit 1063 is an article by Dondeti and others entitled Bioadhesive And Formulation Parameters Affecting Nasal Absorption.

Thank you, Your Honor.

THE COURT: Mr. Berghoff.

MR. BERGHOFF: Your Honor, in addition, I believe both parties --

THE COURT: By the way, those exhibits are admitted.

(Above-referenced exhibits received in evidence.)

MR. BERGHOFF: I believe both parties have the same housekeeping matter of deposition designations.

THE COURT: I wanted to talk about that, and find out from you, in your view, how critical these items are, and whether, in advance of our anticipated next meeting, which I indicated yesterday would likely be June the 9th, I would need to review these matters.

MR. BERGHOFF: Speaking on behalf of plaintiffs, we would like to be sure before we close our case that the designations are entered into the record so that we can refer to them in the proposed findings of fact and conclusions of law and in the later oral argument.

I would be very hesitant to suggest anything with respect to whether and when Your Honor had to review them.

THE COURT: Well, obviously, we have heard testimony. I have benefited from that. I just wanted to determine from you your views as to how critical it would be that I read certain designations.

MR. HURST: Our view, Your Honor, is it is not necessary for you to read the designations. We would also like to have them in the record. To the extent we want to cite to them for further support, then you can have them for your reference, but it is not necessary for you to read through our designations.

THE COURT: Great.

So I have indicated an unwillingness to get

involved in the discussion. Have you been able to work that out, your designations and counter-designations?

MR. HURST: We have, Your Honor.

THE COURT: Whatever they are, they are agreed upon, and you can -- they are admitted as far as I am concerned at this stage, and you can in some way identify them.

MR. BERGHOFF: We will submit them to your clerk, Your Honor.

THE COURT: Do you think you might want to do a stipulation of some type? I don't know.

MR. HURST: A stipulation in terms of the admissibility of the deposition designations?

THE COURT: They are admitted. Just what they are.

MR. BERGHOFF: Yes. We will come up with a list that indicates ours and theirs on one piece of paper.

THE COURT: Just in the event, in the unlikely event, or likely event that this finds its way to the Fed. Circuit, which it may well, you have a record up there that's accurate.

MR. HURST: We will work on a stipulation and have it filed in the record.

THE COURT: I think I am going to follow through with the plan that I previewed yesterday. I would like some

simultaneous submissions of proposed findings by the close of business on May the 30th. Is that do-able in your view?

MR. BERGHOFF: Yes, Your Honor.

MR. HURST: Yes, Your Honor.

THE COURT: Is 15 pages sufficient?

MR. HURST: Yes, Your Honor.

MR. BERGHOFF: Yes, Your Honor.

MR. HURST: Conclusions of fact and law?

THE COURT: Yes. I am going to issue an order. But at the present time I would like to pencil in 8:30 on June 9th. I am supposed to be on trial on another patent matter. So we will have a jury empaneled at that time. But what my plan would be would be to start a little earlier, restart this case at that time, at least for the purpose of the Court hearing some form of oral argument. And it would be my intention to announce a ruling that morning.

(Counsel respond "Thank you, Your Honor.")

THE COURT: Thank you, counsel.

(Court recessed at 12:15 p.m.)

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Reported by: Kevin Maurer and Brian P. Gaffigan